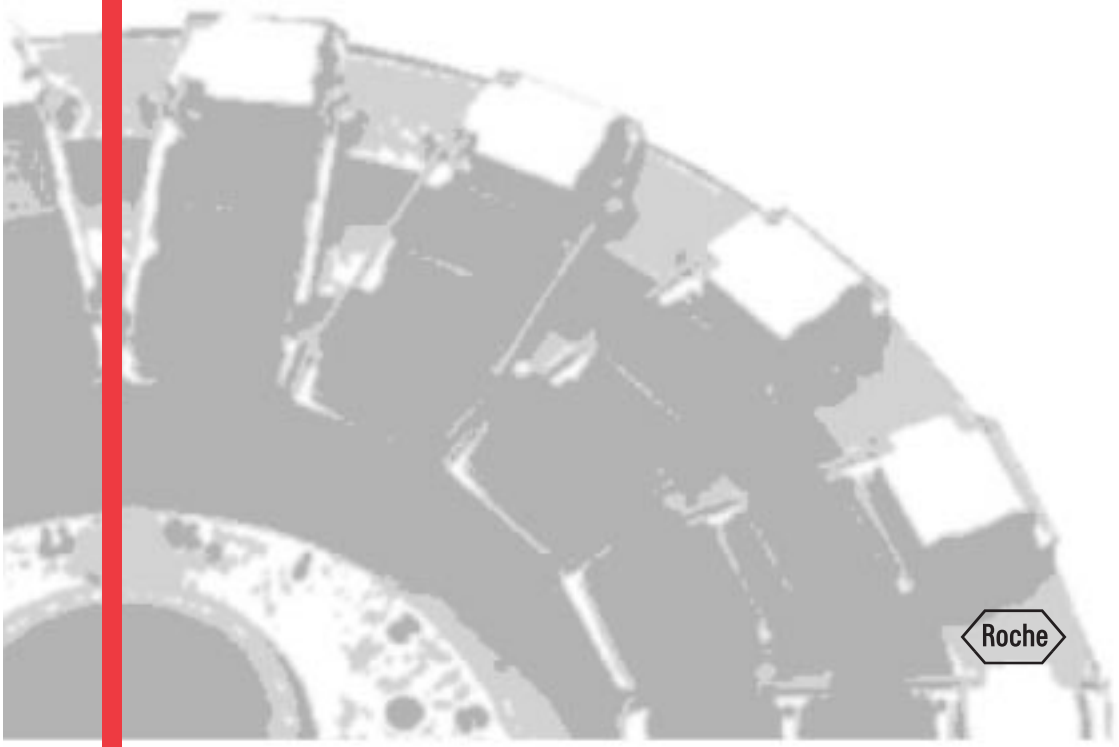
Tutorial Guide

Roche Diagnostics Elecsys® 2010 System Operator's Manual



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Chapter 1
Overview

1.0 Overview

Introduction

This Tutorial Guide contains quick reference procedures for operating the Roche Diagnostics Elecsys 2010 Immunoassay Analyzer. This Tutorial Guide can be used for training purposes. More detailed information can be found in the Reference Guide, Software Guide and User's Guide.

In the Tutorial Guide, you will find:

- daily operating procedures in step by step format
- daily maintenance procedures
- step by step instructions for procedures that are not part of the daily operating routine, but are tasks an average operator is required to perform.

If the procedure described in the section is specific to the disk system, the header will read as in the following example:

2.3 Initiate Calibration – Disk System

If the procedure described in the section is specific to the rack system, the header will read as in the following example:

2.4 Initiate Calibration – Rack System

If the procedure described in the section applies to both the disk and rack systems, then there is no identifier after the section. Refer to the following example:

2.1 Power ON.

Chapter 2

Daily Operation

2.1 Power ON

Introduction

Before processing any samples, you must check for the presence of the data disk, power ON the external printer and analyzer, and log on the software with your operator ID.

Check Data Disk

Check that the data disk is in the disk drive by opening the door on the front panel.

Check data disk

Power the Printer ON

If the printer is not already ON, power it ON. The power switch is located on the front right of the printer. Press the switch once. When the printer is ON, the green light is illuminated. Also check your printer paper supply and make sure it is adequate.

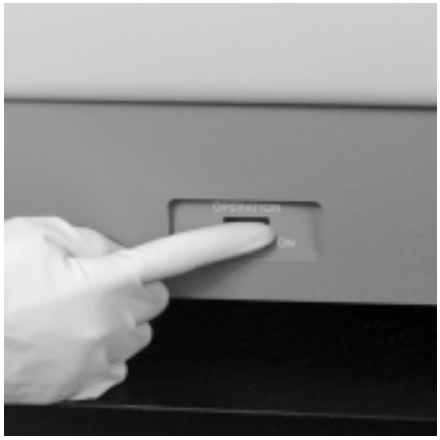
Printer type may vary by country. Refer to the appropriate printer documentation for details.

Printer ON/OFF switch location

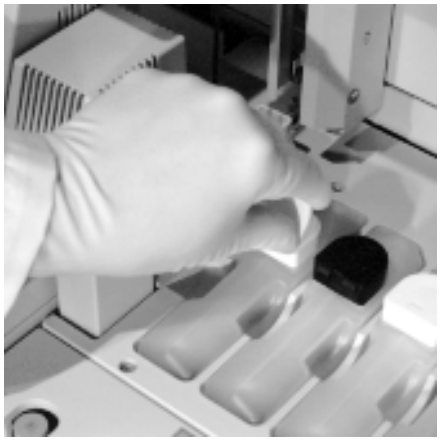
Power the Analyzer ON

The analyzer is powered ON/OFF by the operation switch located on the front panel. Place the switch in the “ON” position by pressing on the right side of the switch. A small green light on the switch is illuminated when the system is ON.

After powering ON the analyzer, open the lids on the ProCell and CleanCell bottles.



Operation ON/OFF switch location



Open lids of ProCell/CleanCell

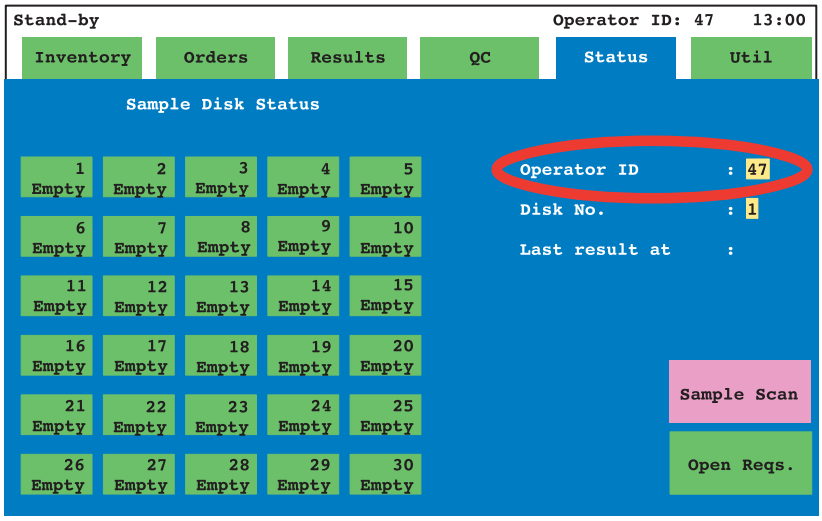
2.1 Power ON

Log On

After a short period of time, what appears on the touchscreen is the last screen the software was in when the analyzer was turned OFF.

If you switch on the analyzer and screen remains black, then check if the circuit breaker is OFF. If the analyzer was powered OFF at the circuit breaker, then after power ON, the introductory screen appears. Carefully check the reagents on the analyzer as power to the peltier units controlling reagent disk temperature was not active.

Use the following procedure to enter your operator ID number.

STEP	ACTION
1	Touch Status to enter the STATUS screen shown below for the disk system. The `Operator ID` field remains in the same place on the screen regardless of which system is used. 
2	Touch the `Operator ID` field. Type in your laboratory-assigned identification number. Use a number from 1 - 99.
3	Press Enter.

2.2 Inventory Checks

Introduction

The following are inventory checks that you should follow before processing samples for the day.

Perform Visual Checks

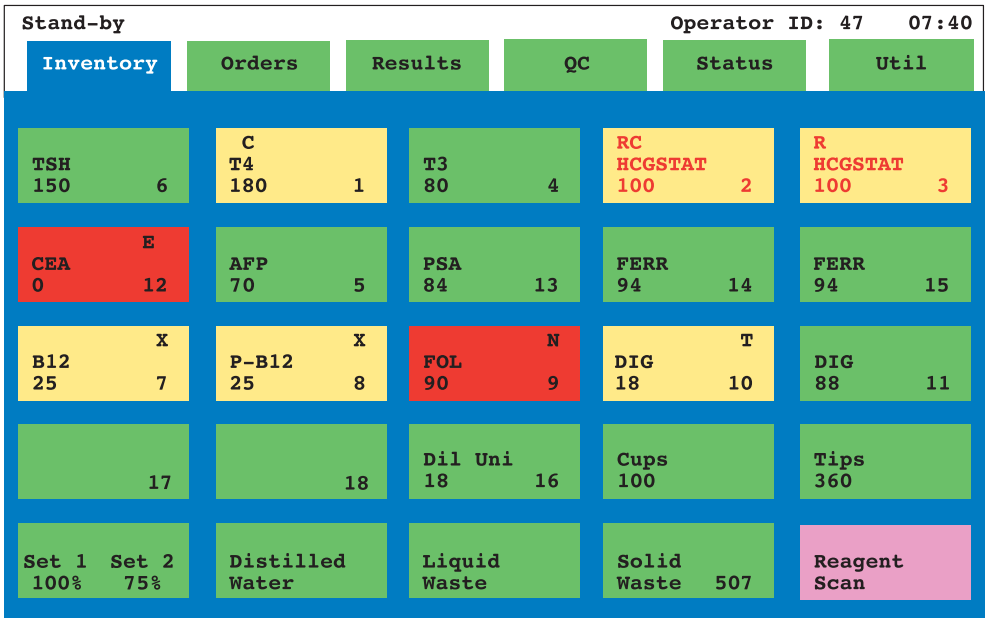
Visually inspect the following components, and clean or adjust as necessary.

Check that:

- probes are in good condition and not dirty
- tubing is not pinched or bent
- pipettors are free of bubbles. If bubbles exist, prime the appropriate pipettor.
- all surfaces in the area of the pipetting station and incubator are clean and free of debris. Liquid spilled on the pipetting station or incubator could cause tips or cups to stick, thereby potentially causing gripper alarms.

Access INVENTORY Screen

Touch Inventory to access the INVENTORY screen. Based on the information seen on the screen, you may perform the following checks (represented as headings in this section), or proceed directly to the Section 2.3, Initiate Calibration – Disk System or Section 2.4, Initiate Calibration – Rack System.

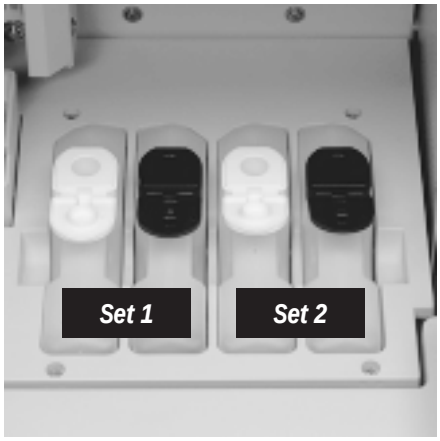


INVENTORY screen

2.2 Inventory Checks

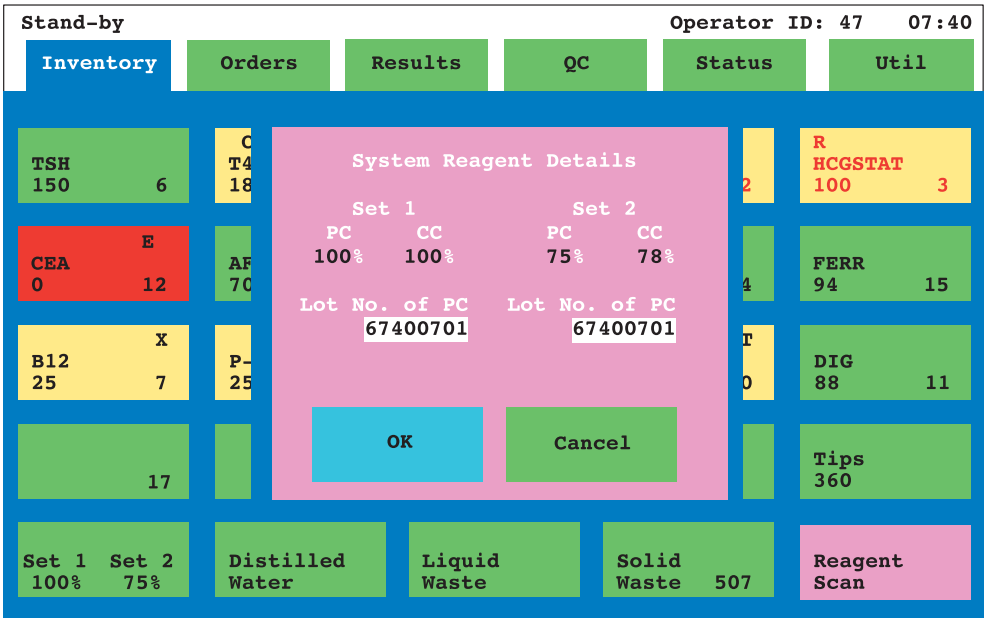
Check System Reagents

Replace ProCell and CleanCell as needed. The system reagent button is green if Set 1 and Set 2 are > 30%. The button is yellow if Set 1 and Set 2 are > 0% and < 30%. The button is red if Set 1 and Set 2 are 0%.



Check ProCell and CleanCell

To check the level in a system reagent bottle set, touch the system reagent button. This accesses the 'System Reagent Details' pop-up window and displays the percentage of reagent in each bottle. It is in this window that you can enter the lot number of ProCell. This lot number is then printed on the Inventory report.



'System Reagent Details' pop-up window

2.2 Inventory Checks

There are photosensors located in positions 2 and 3 of the system reagent compartment. If you remove a bottle from one of the positions containing a photosensor and the volume in that bottle is 100%, the analyzer considers that bottle set to be a “new” bottle set even if the bottle has been on the analyzer for several hours or days. The analyzer waits 15 minutes for temperature equilibration before using what it considers a “new” bottle set.

System reagent positions

If you must load two new bottle sets of ProCell/CleanCell, then load these new bottles as your first inventory check. Therefore, by the time you are ready to begin operation, the system reagents should be at temperature. If they are not, you will receive ProCell/CleanCell reagent temperature alarms. For further information on these alarms, refer to Chapter 3, Instrument Alarms – *User’s Guide*.

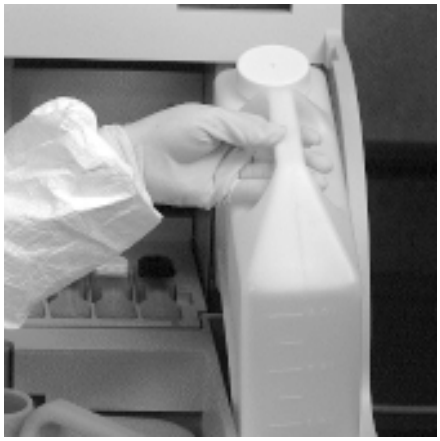
The bottles on the right (Set 2) are consumed first. If replacing the bottles on the right, move the bottles from the left (Set 1) to the right. Then load the new bottles in positions 1 and 2.

2.2 Inventory Checks

Check Distilled Water Container

If the button on the screen indicating distilled water is red, the container is empty. Fill the container with distilled water and return it to the analyzer.

Clean the container if it appears dirty or contaminated. For detailed instructions, refer to Chapter 4, Maintenance – *User's Guide*.



Check distilled water container

Check Liquid Waste Container

If the button on the screen indicating liquid waste is red, the waste container needs to be emptied. Treat the waste from the waste container as potentially infectious. You may add an appropriate volume of a germicidal agent (as directed in its product labeling) to the empty liquid waste container before processing samples. Return the container to the analyzer. Make sure that you remove the blue lid from the container.

Empty liquid waste container

DO NOT USE BLEACH in the liquid waste container. Bleach combined with the contents in the liquid waste could cause potentially harmful fumes.

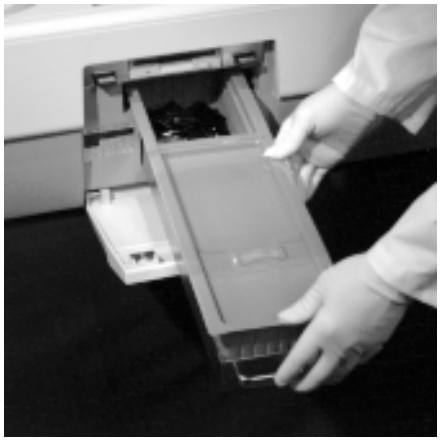
Handle waste as potentially infectious!

Clean the container if it appears dirty or contaminated. For detailed instructions, refer to Chapter 4, Maintenance – *User's Guide*.

Check Solid Waste Tray

The button on the INVENTORY screen turns red when the count reaches 800. Check the solid waste tray and replace with a new Clean-Liner, if necessary. Make sure that the opening of the Clean-Liner is facing towards the back of the analyzer and that the sliding door on the liner is open.

The software counts the tips and cups used during the course of operation. When the analyzer senses that the solid waste tray was removed, the counter resets to “0” (zero). Therefore, if you remove the solid waste tray, we also recommend that, at the same time, you discard the solid waste or replace the Clean-Liner. Check for stray cups or tips in the compartment prior to replacing the solid waste tray.

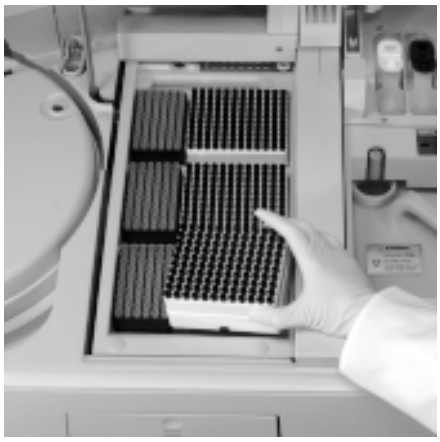


Check solid waste tray

Check Assay Cups and Tips

The Cup button turns yellow when the count is < 60 cups. The Tip button turns yellow when the count is < 120 tips. The button(s) turn red when the cup or tip count is 0 (zero). Replenish the analyzer with new cup or tip trays, if necessary. *Do not add or remove single tips or cups from the trays.*

Make sure the trays are seated properly. The trays are keyed and should fit securely on the analyzer.

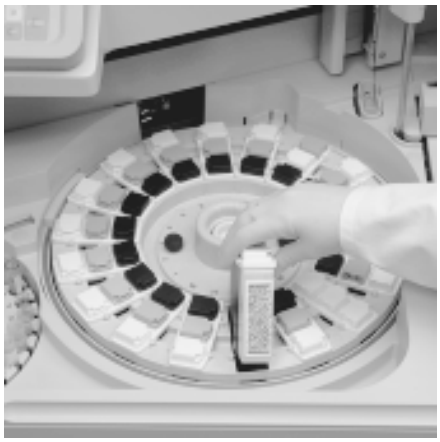


Load new cup or tip trays

2.2 Inventory Checks

Load New Reagents

You can load a maximum of 15 assays on the analyzer at one time. If you plan to run assays that currently are not stored on the analyzer (as reflected by the INVENTORY screen), you must allow them to reach reagent disk temperature (20 ± 3 °C) before starting analysis. Or, place the reagent packs on the reagent disk for a minimum of 45 minutes prior to starting operation. Reagents on the reagent disk are stored in temperature controlled conditions. No additional time is required if all assays to be performed are stored on the reagent disk. If new reagents were loaded, be sure to replace the reagent disk cover. The analyzer will not operate without the cover on the disk.



Load new reagents, if necessary

If the INVENTORY screen displays a red test button with the letter "E," it means that the reagent pack is empty and you should place a new reagent pack on the disk.

If you remove a reagent pack from the reagent disk, be sure to securely snap the lids closed before returning the pack to refrigerated storage.

If you added or removed a reagent from the reagent disk, the analyzer senses that the cover was removed and automatically performs a reagent scan when Start is pressed from Stand-by. The scan updates the inventory on the analyzer. During the reagent scan the status line at the top of the screen flashes "Scanning." Refer to the status line below.

INVENTORY screen status line during a reagent scan

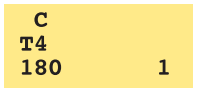
When the scan is complete, the INVENTORY screen indicates the status of each reagent pack on the reagent disk.

A green test button indicates that a valid calibration exists.

A yellow test button with an “R” and red text indicates a new reagent pack with no Lot calibration (L-Cal) available. Another reagent pack for the assay was prioritized by the system for L-Cal or you manually deselected the L-Cal (i.e., the button previously displayed “RC” and you selected “Calib. Req. Off” in the ‘Reagent Details’ pop-up window).

A yellow test button with an “RC” and red text indicates that an L-Cal is requested by the system. If there is more than one reagent pack of a single lot on the reagent disk, only the reagent pack to be calibrated according to automatic calibration (i.e., calibration by loading) displays “RC.” This calibration can be changed in the assay ‘Reagent Details’ pop-up window. If an “X” also appears in the upper right corner of this button, the reagent is expired and the calibration generated by the analyzer can only be a reagent pack calibration (R-Cal). Samples performed using expired reagent are flagged by the software with data alarm 52, “Expired reagent pack.”

A yellow test button with a “C” indicates that calibration was manually requested in ‘Reagent Details’ or the daily calibration expired. Daily calibration does not apply to quantitative assays.



A red test button with an “N” indicates that the test cannot be calibrated. The corresponding pretreatment reagent is missing from the reagent disk.

A yellow test button with a “T” indicates the minimum available tests threshold for the assay was reached. The threshold is defined in the ‘Test Conditions Details’ pop-up window/TEST CONDITIONS screen/UTIL folder.

A yellow test button with an “X” indicates the reagent pack is expired.

Calibration recommendations are specified in the reagent kit package insert. Touch the corresponding test button to open the ‘Reagent Details’ pop-up window and check the `recommended at` L-Cal date or `recommended at` R-Cal date.

The L-Cal date is primarily for high volume users (reagent pack used in - 7 days). The R-Cal date is primarily for lower volume users (reagent pack in use > 7 days).

Each laboratory should establish a quality control program and establish its own control ranges. If the values fall outside the control ranges, each laboratory should establish guidelines for corrective measures.

2.2 Inventory Checks

Prepare Calibrators and Controls

Based on the reagent scan just performed, prepare calibrators, if necessary. Not all calibrators require reconstitution; most are ready to use. Refer to the specific calibrator package insert.

Prepare controls, if necessary. Follow instructions on the appropriate package insert. Make sure that the calibrators and controls are at room temperature before placing them on the sample disk or rack.

Always use immunoassay controls and calibrators at room temperature. Allow adequate time for all calibrators and controls to reach room temperature before processing samples. Remember, calibrator stability at room temperature varies. ***Do not leave the calibrators out at room temperature too long.*** *Check the package insert for details.*

What's Next?

When you have completed the inventory checks, proceed to the Section 2.3, Pre-Operation Data Management – Disk System or Section 2.4, Pre-Operation Data Management – Rack System, to delete open requisitions, if necessary.

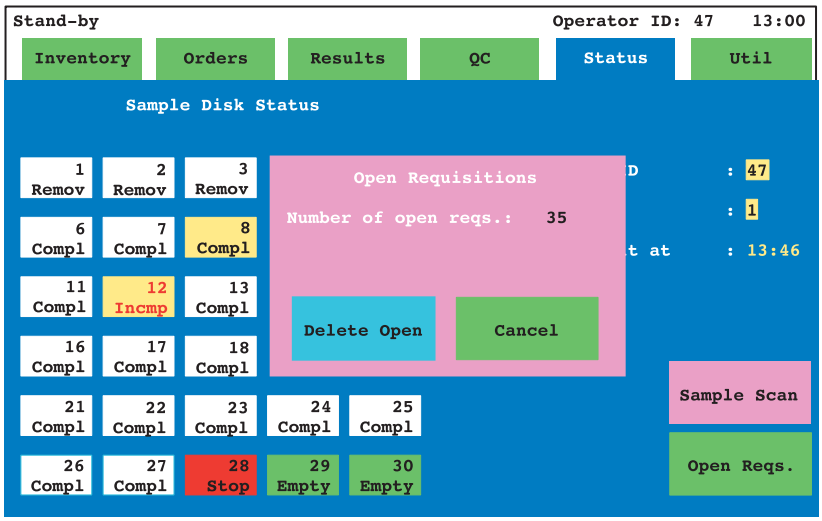
2.3 Pre-Operation Data Management – Disk System

Introduction

Open requisitions represent sample orders not yet processed. Delete open requisitions as necessary if unprocessed requisitions exist in the system.

Procedure

Follow the procedure below to delete miscellaneous open requisitions in the system. You can only delete open requisitions when the system is in Stand-by.

STEP	ACTION
1	Touch Status to access the STATUS screen.
2	Touch the Disk No. field, type the disk number (0-9) and press Enter.
3	Touch Open Reqs. to access the 'Open Requisitions' pop-up window. 
4	Touch Delete Open to delete any open requisitions.
5	Repeat 2 - 4 for each sample disk.

What's Next?

When you have completed data management, proceed to Section 2.5, Initiate Calibration/Control Measurement – Disk System, to calibrate the analyzer.

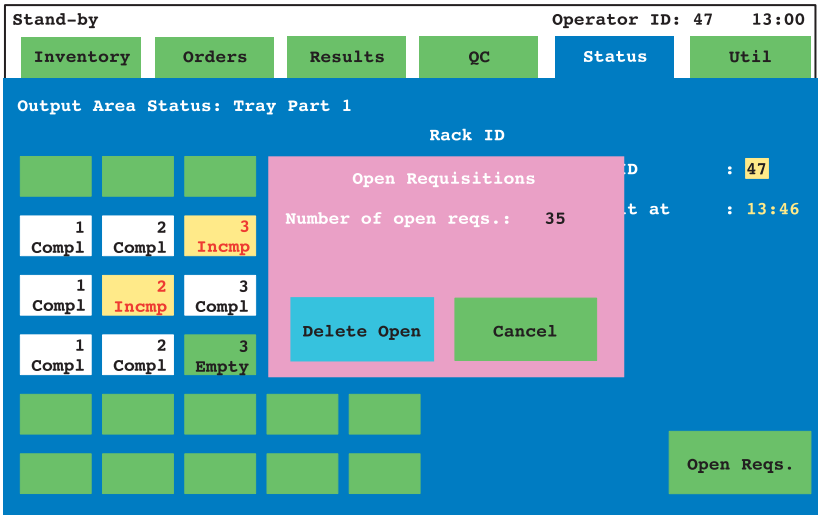
2.4 Pre-Operation Data Management – Rack System

Introduction

Open requisitions represent sample orders not yet processed. Delete open requisitions as necessary if unprocessed requisitions exist in the system.

Procedure

Follow the procedure below to delete miscellaneous open requisitions in the system. You can only delete open requisitions when the system is in Stand-by.

STEP	ACTION
1	Touch Status to access the STATUS screen.
3	Touch Open Reqs. to access the 'Open Requisitions' pop-up window. 
3	Touch Delete Open to delete any open requisitions.

What's Next?

When you have completed data management, proceed to Section 2.6, Initiate Calibration/Control Measurement – Rack System, to calibrate the analyzer.

2.5 Initiate Calibration/Control Measurement – Disk System

Introduction

Calibrate any reagent packs based on information indicated in the INVENTORY screen or on information in the 'Reagent Details' pop-up window.

Calibration does not need to occur as a separate step. Calibration can be performed along with your patient samples.

Perform Bar Code Card Scan

If a new lot of calibrators or controls is used, perform a bar code card scan. Follow the procedure below.

STEP	ACTION
1	Touch Util to access the UTIL screen.
2	Touch Calibration Data or Control Definition.
3	Insert the calibrator or control bar code card into the card reading station as in the photo to the right. The bar code must face toward the back of the analyzer. Push the card as far down as it will go into the station.  **Insert bar code card into station**
3	Touch BC Card Scan to initiate the scan. The status line changes as follows:  The bar code card was successfully scanned when you hear the bar code reader beep. Do not remove the card until the analyzer returns to Stand-by.
4	Repeat steps 2 - 3 for each card to be scanned.

2.5 Initiate Calibration/Control Measurement – Disk System

Load the Sample Disk and Program Calibration

As a result of the use of single analyte calibrators, programming test calibration on the analyzer is very easy. Simply place one set (Cal 1 and Cal 2) of open, bar code-labeled calibrator vials on the sample disk. When the calibrator bar code is scanned by the bar code reader, calibration is automatically requested for the assay. This is known as calibration by loading. ***Both levels of an assay's calibrators must be next to each other on the sample disk.***

Load the sample disk

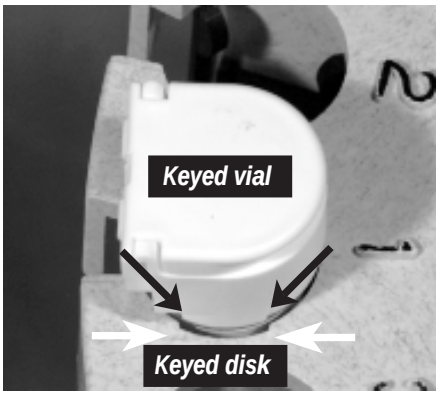
Load open, bar-coded control vials ***directly*** after a CalSet for control of calibration to occur, or leave an ***open sample position*** after the CalSets to run controls on all assays calibrated. For more detailed information on control of calibration, refer to Section 3.1, How To Load Controls for Control of Calibration – Disk System.

When a control vial is scanned, test selections programmed via the CONTROL DEFINITIONS screen, are automatically performed.

If no control test selections were programmed, the system automatically queries a Host system for test selections when interfaced.

If no control test selections are available on a Host system, the control is not processed and appears with an "Occup" status on the STATUS screen.

The CalSet vials, control vials and sample disk are keyed so the vials are placed on the disk correctly (i.e., with the bar code facing outward and lid straight up). The notch is found on the left side of the disk position. Refer to the photos below.



Keyed vial and sample disk

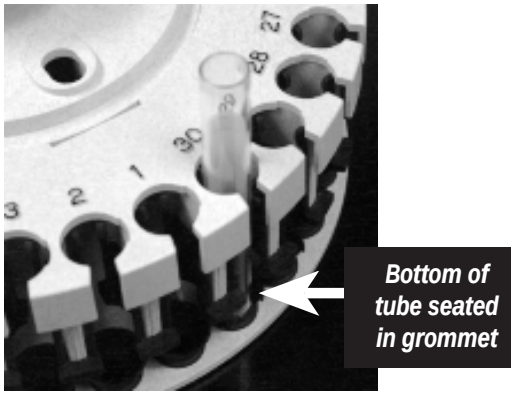
Loaded vial on sample disk

2.5 Initiate Calibration/Control Measurement – Disk System

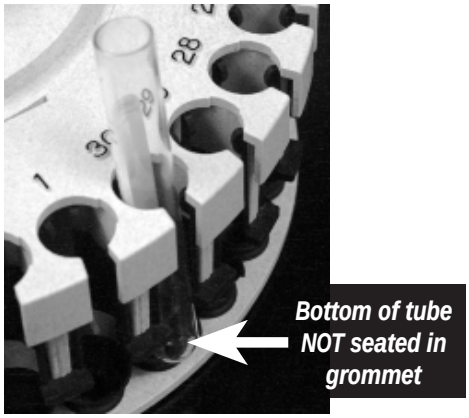
Placement of 13 mm Sample Tubes on the Sample Disk

If a 13 mm tube is improperly placed on the sample disk, the S/R probe may attempt to sample outside of the tube. The liquid level detection (LLD) signal would be detected by the S/R probe contacting the outside of the tube. Since LLD signal is detected, no alarms are issued. This could potentially result in reporting incorrect results. This problem affects all 13 mm tubes, but 13 x 100 mm tubes are the most susceptible.

This situation can be resolved by paying special attention when placing 13 mm tubes on the sample disk. When the tube is improperly placed, the bottom of the tube is not seated in the black grommet on the bottom of the disk. A quick check of the sample disk before starting the analyzer will alert you if a tube is misaligned. The photos below illustrate the correct and incorrect placement of a 13 x 100 mm tube on the sample disk.

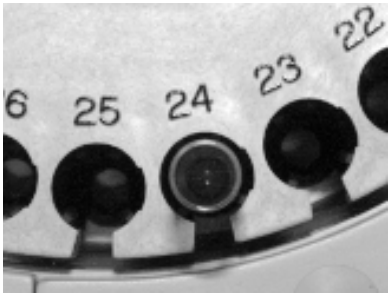


Correct **placement of tube**



Incorrect **placement of tube**

The photos below show the correct and incorrect placement of the same 13 x 100 mm tube on the sample disk of the analyzer. It is still apparent from an overhead view that the tube is misaligned.



Correct placement of tube (overhead view)

Incorrect placement of tube (overhead view)

2.5 Initiate Calibration/Control Measurement – Disk System

Select Non-Roche Controls, If Necessary

Roche Diagnostics provides assayed controls for use on the Elecsys 2010 analyzer. These controls are bar-coded for your convenience. All target values and control ranges are transferred during scans to the software via the control bar code card or reagent bar code and the linear bar code found on each control vial. When the analyzer scans the control vial, the software automatically identifies it as a control and labels it as such in the software and on printouts.

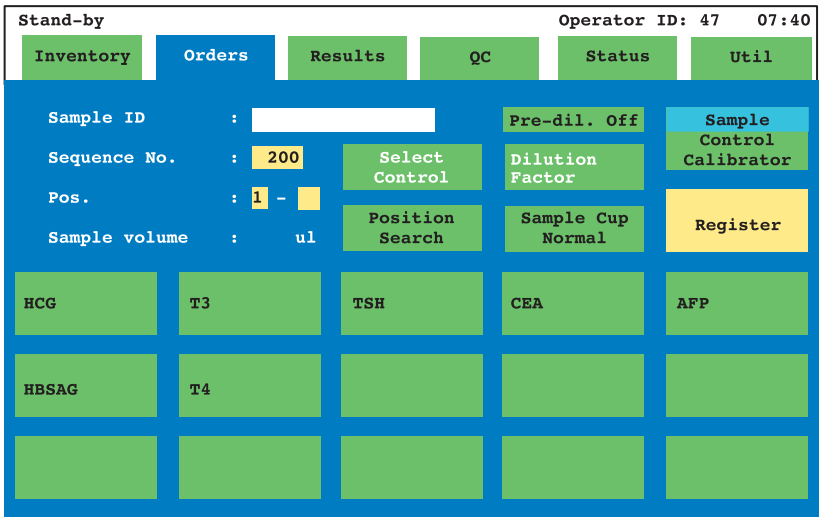
Both Roche and non-Roche controls must be defined before loading on the sample disk. Controls are defined in the CONTROL DEFINITION screen/UTIL folder. Once you select tests for the control level, it is not necessary to order tests on that control level again. For detailed information on defining controls, refer to Section 3.10, How To Define Roche (Bar-Coded) Controls or Section 3.11, How To Define Non-Roche (Non-Bar-Coded) Controls.

Each laboratory should establish a quality control program and establish its own control ranges. If the values fall outside the control ranges each laboratory should establish guidelines for corrective measures.

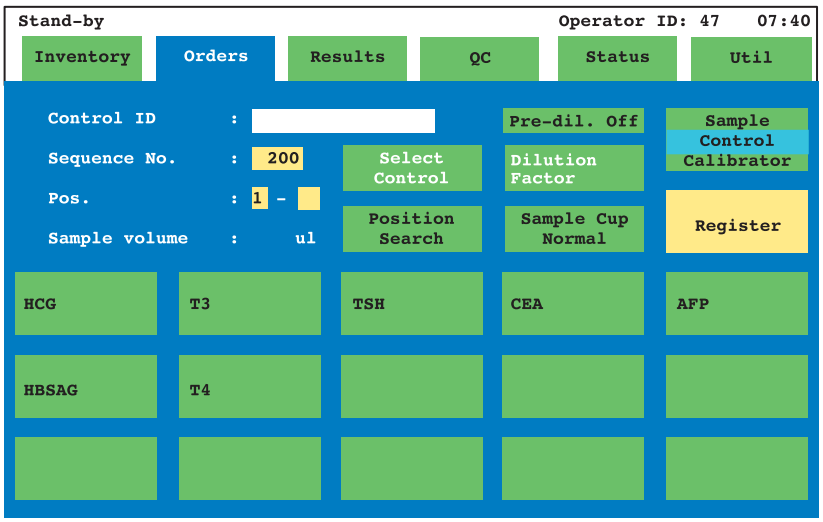
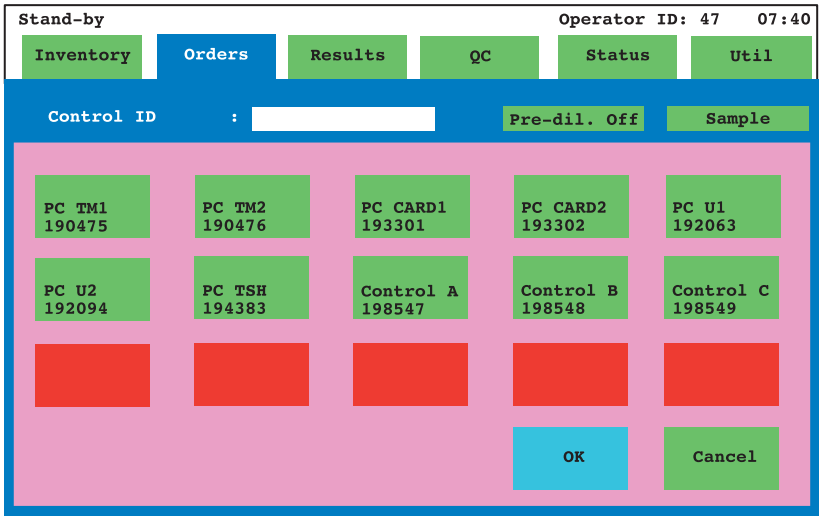
You must validate control values using established QC procedures (e.g., Levy-Jennings, multi-rule Shewhart, etc.). Validation may be done manually or via a program that utilizes one of the aforementioned QC procedures. Follow your laboratory policy regarding control validation.

Follow the instructions below to select a non-Roche control, if necessary. Use this procedure to select Roche controls with damaged or no bar codes.

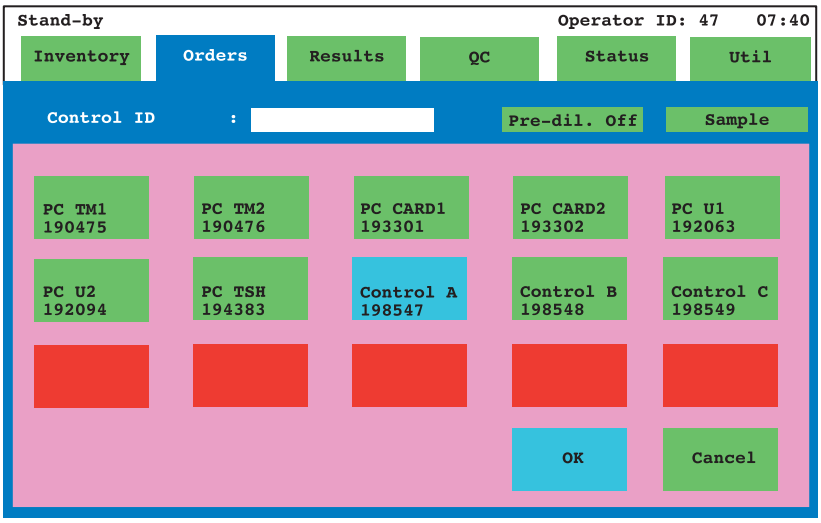
STEP	ACTION
1	Touch Orders to access the ORDERS screen.



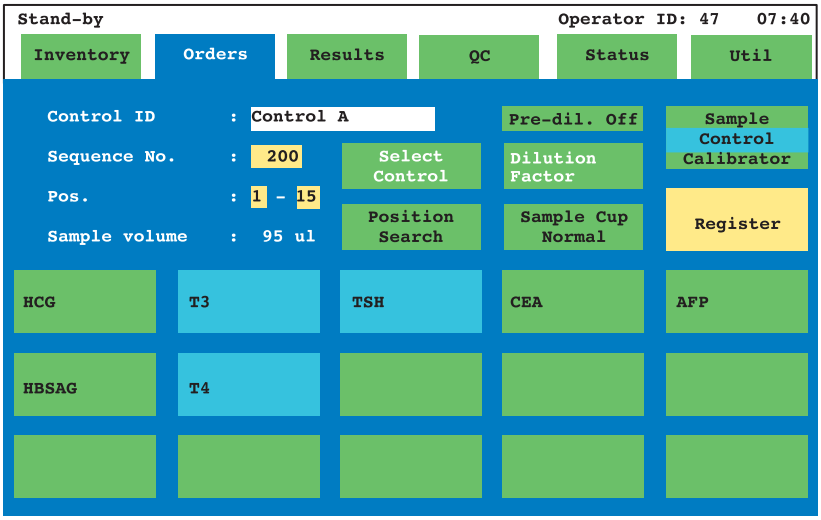
2.5 Initiate Calibration/Control Measurement – Disk System

STEP	ACTION
2	Touch the Sample / Control / Calibrator button to toggle to the `Control` selection. 
3	Touch Select Control to access the 'Select Control' pop-up window. 

2.5 Initiate Calibration/Control Measurement – Disk System

STEP	ACTION
4	Touch the appropriate control button. The button turns light blue when selected. 
5	Touch OK to close the window and return to the ORDERS screen. Now, the available assays that were previously defined in CONTROL DEFINITION screen are selected.
6	Touch test buttons to select/deselect additional assays, if necessary. *Tests can only be selected if they were previously activated in the CONTROL DEFINITION screen.*

2.5 Initiate Calibration/Control Measurement – Disk System

STEP	ACTION
7	Touch the second Pos. field, type the sample disk position (1-30) and press Enter. 
8	If you are running in the multiple disk mode, touch the first disk Pos. field. Type a disk number (0-9) and press Enter.
9	Touch Register. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • The Pos. increments by one.
10	Repeat steps 2 - 9 until all non-Roche controls are programmed.
11	Load Stop bar code.

Print a Work List (Optional)

After programming your controls, you can print a work list of all positions on the sample disk. Print the work list by pressing Doc while in the ORDERS screen. For details on the work list, refer to Chapter 8, Reports – *Software Guide*.

2.5 Initiate Calibration/Control Measurement – Disk System

Initiate Calibration

Press (Start) to initiate operation.

Be sure to remove calibrators and controls from the sample disk when sampling is complete. Close the lids and return them to the refrigerator.

What's Next?

When your calibration is complete, proceed to Section 2.7, Calibration Validation, to evaluate your calibration.

2.6 Initiate Calibration/Control Measurement – Rack System

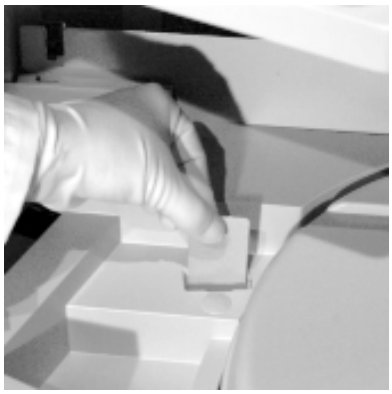
Introduction

Calibrate any reagent packs based on information indicated in the INVENTORY screen or on information in the 'Reagent Details' pop-up window.

Calibration does not need to occur as a separate step. Calibration can be performed along with your patient samples.

Perform Bar Code Card Scan

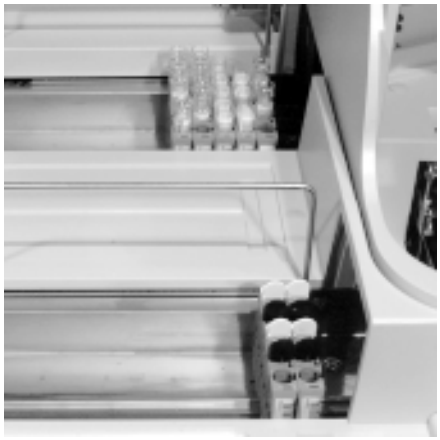
If a new lot of calibrators or controls is used, perform a bar code card scan. Follow the procedure below.

STEP	ACTION
1	Touch Util to access the UTIL screen.
2	Touch Calibration Data or Control Definition.
3	Insert the calibrator or control bar code card into the card reading station as in the photo to the right. The bar code must face toward the back of the analyzer. Push the card as far down as it will go into the station.  **Insert bar code card into station**
3	Touch BC Card Scan to initiate the scan. The status line changes as follows:  The bar code card was successfully scanned when you hear the bar code reader beep. Do not remove the card until the analyzer returns to Stand-by.
4	Repeat steps 2 - 3 for each card to be scanned.

2.6 Initiate Calibration/Control Measurement – Rack System

Load the Sample Racks and Program Calibration

As a result of the use of single analyte calibrators, programming test calibration on the analyzer is very easy. Simply place one set (Cal 1 and Cal 2) of open, bar code-labeled calibrator vials on a sample rack. When the calibrator bar code is scanned by the bar code reader, calibration is automatically requested for the assay. This is known as calibration by loading. ***Both levels of an assay's calibrators must be next to each other on the sample rack. Do not split a calibrator set between racks.***



Load the sample rack

Load open, bar-coded control vials ***directly*** after a CalSet for control of calibration to occur, or leave an ***open sample position*** after the CalSets to run controls on all assays calibrated. For more detailed information on control of calibration, refer to Section 3.2, How To Load Controls for Control of Calibration – Rack System.

When a control vial is scanned, test selections programmed via the CONTROL DEFINITIONS screen, are automatically performed.

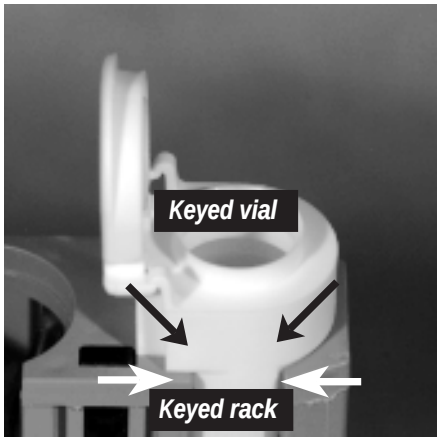
If no control test selections were programmed, the system automatically queries a Host system for test selections when interfaced.

If no control test selections are available on a Host system, the control is not processed and appears with an "Occup" status on the STATUS screen.

2.6 Initiate Calibration/Control Measurement – Rack System

The CalSet vials, control vials and sample racks are keyed so the vials are placed on the rack correctly (i.e., with the bar code facing outward through the rack opening and lid straight up). The notch is found on the open side of the sample rack. Refer to the photos below.

Loaded vial on sample rack



Close up of loaded vial on sample rack

Loading Sample Tubes on the Sample Rack

When loading primary or secondary sample tubes on sample racks, verify that the tubes are straight in the racks and the bar codes, if applicable, are visible through the openings on the rack so the bar code reader scans them properly.

2.6 Initiate Calibration/Control Measurement – Rack System

Select Non-Roche Controls, If Necessary

Roche Diagnostics provides assayed controls for use on the Elecsys 2010 analyzer. These controls are bar-coded for your convenience. All target values and control ranges are transferred during scans to the software via the control bar code card or reagent bar code and the linear bar code found on each control vial. When the analyzer scans the control vial, the software automatically identifies it as a control and labels it as such in the software and on printouts.

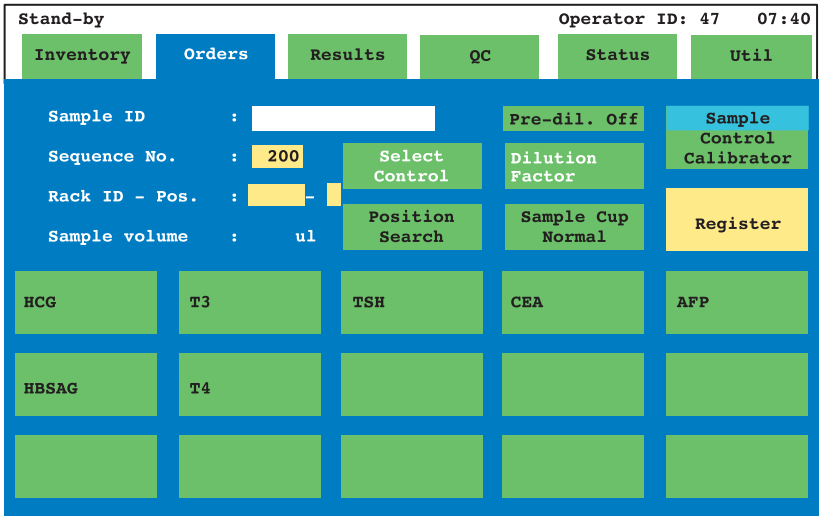
Both Roche and non-Roche controls must defined before loading on the sample rack. Controls are defined in the CONTROL DEFINITION screen/UTIL folder. Once you select tests for the control level, it is not necessary to order tests on that control level again. For detailed information on defining controls, refer to Section 3.10, How To Define Roche (Bar-Coded) Controls or Section 3.11, How To Define Non-Roche (Non-Bar-Coded) Controls.

Each laboratory should establish a quality control program and establish its own control ranges. If the values fall outside the control ranges each laboratory should establish guidelines for corrective measures.

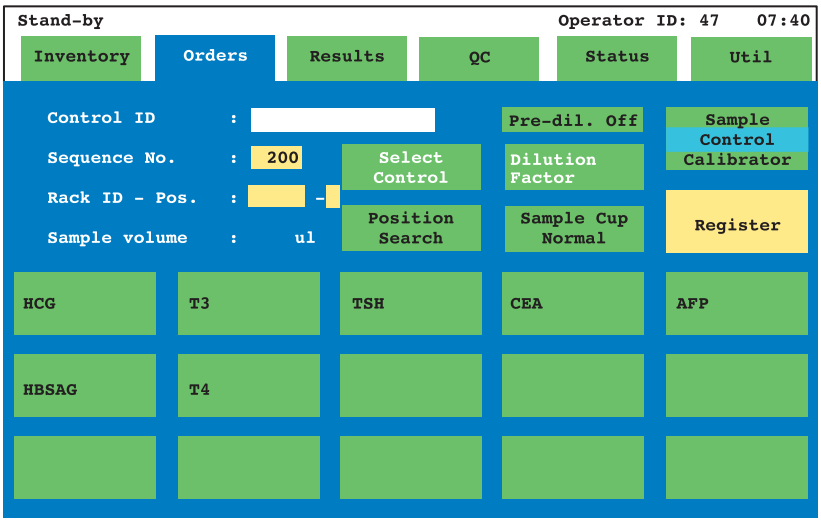
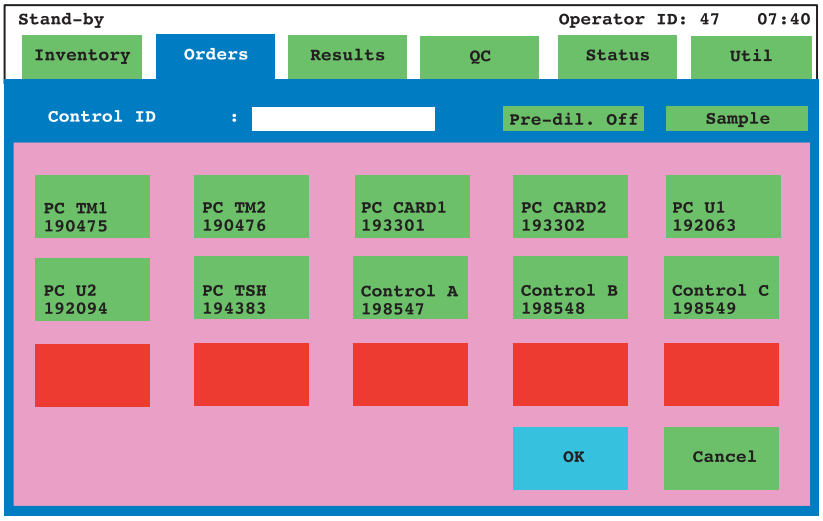
You must validate control values using established QC procedures (e.g., Levy-Jennings, multi-rule Shewhart, etc.). Validation may be done manually or via a program that utilizes one of the aforementioned QC procedures. Follow your laboratory policy regarding control validation.

Follow the instructions below to select a non-Roche control, if necessary. Use this procedure to select Roche controls with damaged or no bar codes.

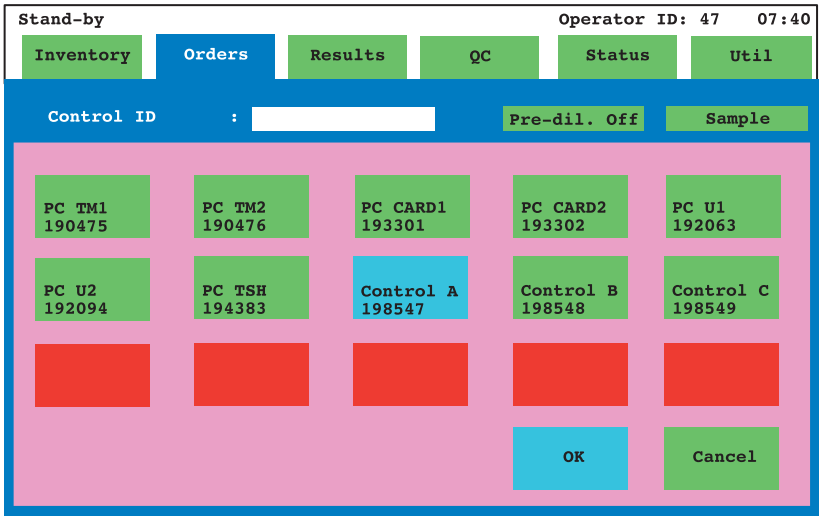
STEP	ACTION
1	Touch Orders to access the ORDERS screen.



2.6 Initiate Calibration/Control Measurement – Rack System

STEP	ACTION
2	Touch the Sample Control Calibrator button to toggle to the `Control` selection. 
3	Touch Select Control to access the 'Select Control' pop-up window. 

2.6 Initiate Calibration/Control Measurement – Rack System

STEP	ACTION
4	Touch the appropriate control button. The button turns light blue when selected. 
5	Touch OK to close the window and return to the ORDERS screen. Now, the available assays that were previously defined in CONTROL DEFINITION screen are selected.
6	Touch test buttons to select/deselect additional assays, if necessary. *Tests can only be selected if they were previously activated in the CONTROL DEFINITION screen.*
7	Touch the `Rack Pos.` field. Type the rack position and press Enter.
8	Touch the `Rack ID` field. Type the rack number and press Enter.
9	Touch Register to register test selections. • The cursor returns to the `Sample ID` field. • The `Sequence No.` increments by one. • For rack positions 1 - 4, the `Rack Pos.` increments by one. For position 5, the `Rack Pos.` returns to 1. • For rack positions 1 - 4, the `Rack ID` remains unchanged. For position 5, the `Rack ID` clears.
10	Repeat steps 2 - 9 until all non-Roche controls are programmed.

2.6 Initiate Calibration/Control Measurement – Rack System

Print a Work List (Optional)

After programming your controls, you can print a work list of all positions on the sample racks. Print the work list by pressing Doc while in the ORDERS screen. For details on the Work List, refer to Chapter 8, Reports – *Software Guide*.

Initiate Calibration

Press Start to initiate operation.

Be sure to remove calibrators and controls from the racks when sampling is complete. Close the lids and return them to the refrigerator.

What's Next?

When your calibration is complete, proceed to Section 2.7, Calibration Validation, to evaluate your calibration.

2.7 Calibration Validation

Introduction

Calibration results print automatically when the calibration is complete (if automatic printing is selected in the DOCUMENTATION SETUP screen). Duplicate count readings of the first and second calibrator are printed as in the example below. The status of the calibration can be determined from the CALIBRATION DATA screen or from the Calibration Data report. You can also view this data from the 'Calibration Data Details' pop-up window.

```
Calibration Data           Operator ID: 10               06/23/1998  09:07
----------------
Lot calibration was successful


Test code                          : TSH
Unit                               : uIU/ml
Lot no. reagent pack               : 194387
Reagent pack number                : 1665
  Exp. date reagent pack           : 06/1998

Lot Calibration
  Lot calibration date             : 05/13/1998
  Reagent pack no. for Lot Calib.  : 1665
  Lot no. of calibrator            : 194414
  Exp. date calibrator             : 02/1999
Recommended at                     : 06/12/1998

R. Pack Calibration
  Reagent pack calibration date    : 05/13/1998
  Reagent pack no. for R. pack cal.: 1665
  Lot no. of calibrator            : 194414
  Exp. date calibrator             : 02/1999
Recommended at                     : 05/20/1998

Calibration Quality Criteria
 Missing values                      ----------
 Monotony of curve                        -----
 Calibration factor                  1.00
 Minimum signal                      ----------
 Deviation of dup. measurements           -----
 System errors                            -----

Calibrators    1. Signal      2. Signal        Target Value
        1 :         1079           1045           0.000 uIU/ml
        2 :        23167          23130            1.48 uIU/ml
```

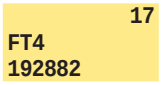
Example of a Calibration Data report

Calibration Status

The calibration status of the test is easily identified on the CALIBRATION DATA screen by the color of the test button. Three colors are used to distinguish calibration status. They are as follows:

Green: Calibration was successful.

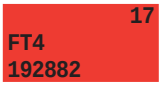
Yellow: Calibration was questionable. You must check the Calibration Data report or view the 'Calibration Data Details' pop-up window to determine which quality criteria were violated. You can release this calibration by touching the test button, followed by the Release button, then OK. If a previous calibration exists, all sample and QC results obtained prior to pressing Release were calculated using the last valid calibration. Review any QC with "Previous Calibration Used" data alarms to determine if patient samples performed at the same time as the yellow calibration may be acceptable.



After releasing the calibration, all subsequent results are calculated using the released calibration. The released calibration is an R-Cal (reagent pack calibration). Repeat QC values to determine the validity of the released calibration.

If the calibration is discarded by touching Reject, then OK, the last valid calibration is used to calculate subsequent sample results.

Red: Calibration failed. The last valid calibration is used to calculate the sample results. All samples are flagged with "Previous Calibration Used."



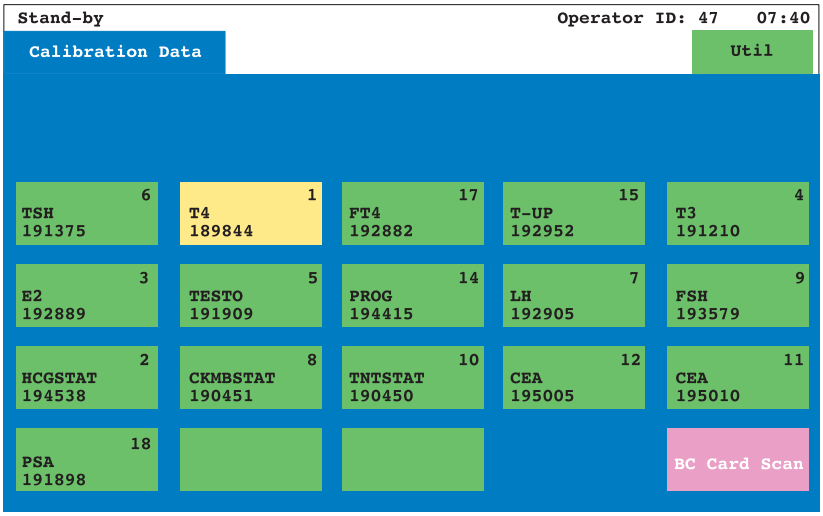
Preceding calibrations can only be used if a valid calibration exists in the software. In the case of rejected questionable calibrations or failed calibrations, perform a new calibration.

For additional information on calibration validation, refer to Section 6.1, Reagent Calibration – *Reference Guide,* Section 7.8, 'Calibration Data Details' pop-up window or Section 8.9, Calibration Data Report – *Software Guide*.

2.7 Calibration Validation

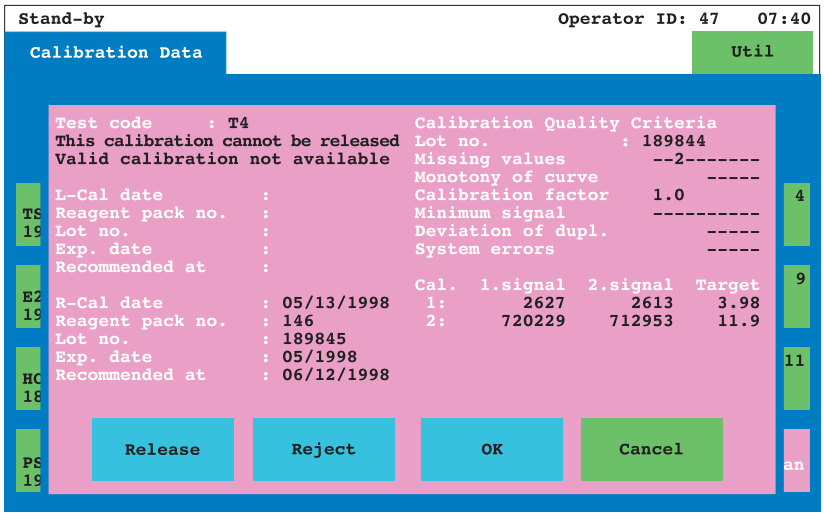
Procedure

Follow the instructions below to view the calibration status.

STEP	ACTION
1	Touch Util to access the UTIL screen.
2	Touch Calibration Data to access the CALIBRATION DATA screen. 
3	The color of the test button determines the status.

IF the color is...	THEN...
green	• calibration was successful. No further action is necessary.
yellow	• calibration was questionable. Proceed to step 4.
red	• calibration failed. Repeat the calibration for the test.

Follow your laboratory protocol regarding questionable or failed calibration results.

STEP	ACTION
4	Review the Calibration Data report for the assay or touch the test button for the assay to access the 'Calibration Data Details' pop-up window. 
5	Determine why the calibration was questionable. Refer to the next subsection, Questionable Calibrations, for further information. • If you wish to accept the calibration, touch Release, then touch OK. • If you wish to reject the calibration, touch Reject, then touch OK. Repeat the calibration for the test.

2.7 Calibration Validation

Questionable Calibrations

If the calibration was questionable (i.e., a yellow test button), you must review the Calibration Data report or the 'Calibration Data Details' pop-up window for the assay and determine the cause. The QC following the questionable calibration was calculated from the last valid calibration and ***cannot*** be used to validate the questionable curve. You must further validate the calibration by performing QC after the calibration has been released. In addition, any patient and control results are flagged with the data alarm 26 – Previous calibration used.

If you wish to repeat patient samples using the newly released calibration, you must reprogram the test requests.

There may be circumstances when the calibration can be released without requiring the samples to be repeated. These circumstances must be determined based on a thorough review of the calibration data for the assay and your laboratory policy. For further information on calibration data, refer to Section 7.8, 'Calibration Data Details' pop-up window or Section 8.9, Calibration Data Report – *Software Guide*.

What's Next?

When calibration validation is complete, proceed to the Section 2.8, Routine Sample Measurements – Disk System or Section 2.9, Routine Sample Measurements – Rack System, to program patient samples.

Remember, calibration does not need to occur as a separate step. Calibration can be performed along with your patient samples.

2.8 Routine Sample Measurements – Disk System

Introduction

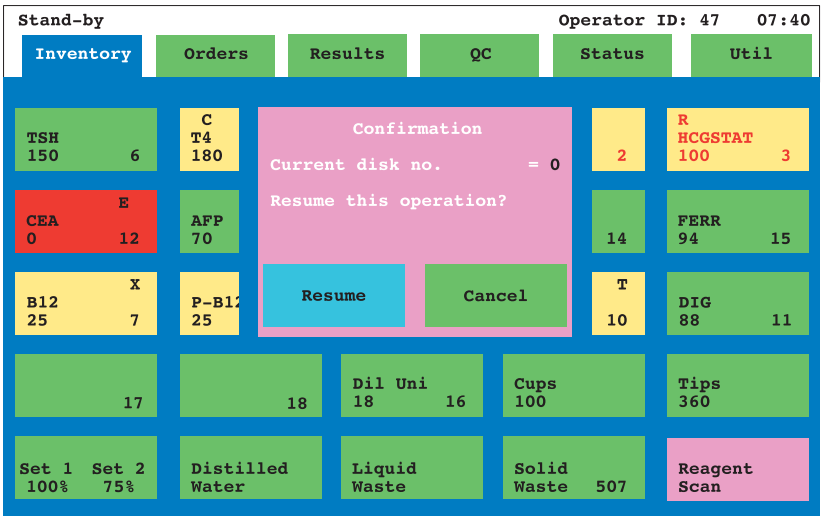
Patient test selections can be made at any time during operation.

Patient Programming for Interfaced, Bar-Coded Samples

Follow the instructions below to program samples when your laboratory is interfaced with a host computer and you are using bar-coded samples.

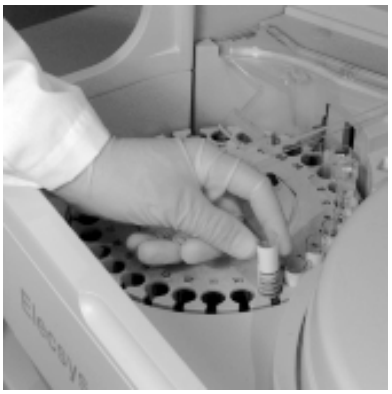
STEP	ACTION
1	Perform sample programming at the host, if necessary.
2	Place the bar-coded samples on the sample disk. Make sure the bar codes are facing out so the bar code reader scans them properly.  **Load bar-coded samples**
3	Place a Stop bar code in the next open position on the disk. *If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.* *If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.*

2.8 Routine Sample Measurements – Disk System

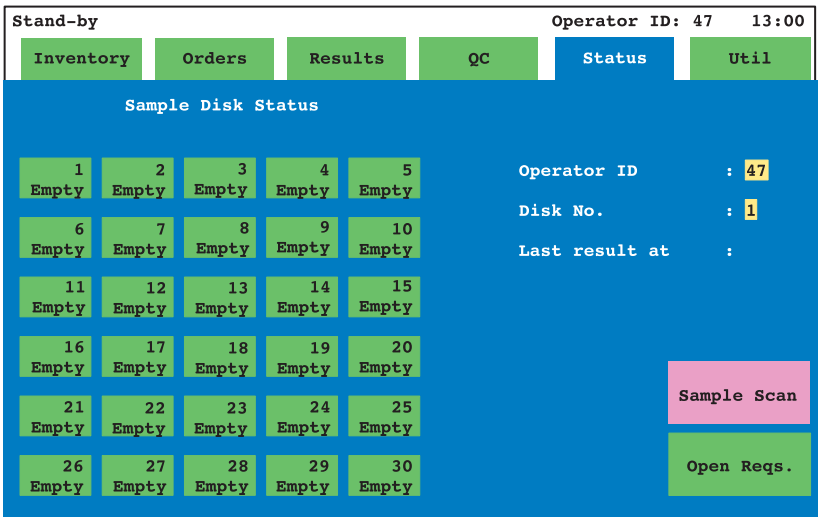
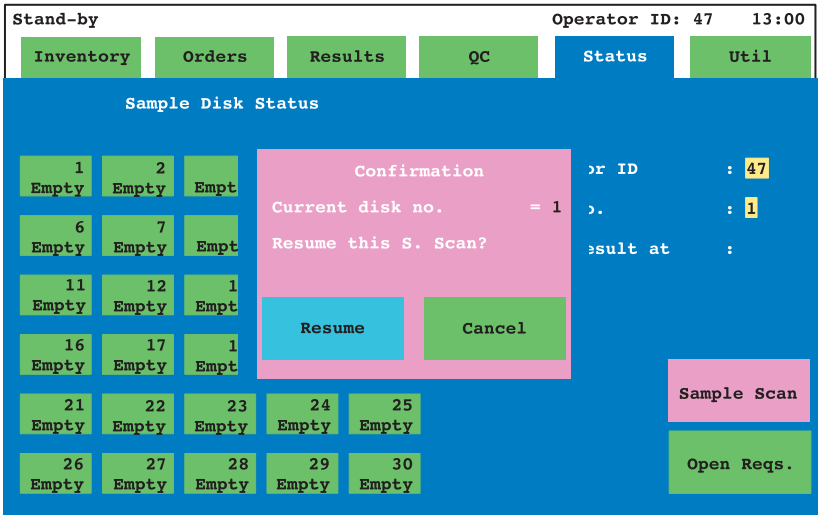
STEP	ACTION
4	Press Start. If running in the multiple disk mode, the following screen appears. Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press Resume. If the disk number is incorrect, press Cancel and enter the correct disk number on the STATUS screen. The correct disk number must be selected for the samples to be processed.  As each bar code is scanned the Elecsys queries the host and receives test requests for the sample. The sequence number and position are automatically assigned during this process. *If the host does not answer within 15 seconds, the position is skipped and the disk advances to the next position.*

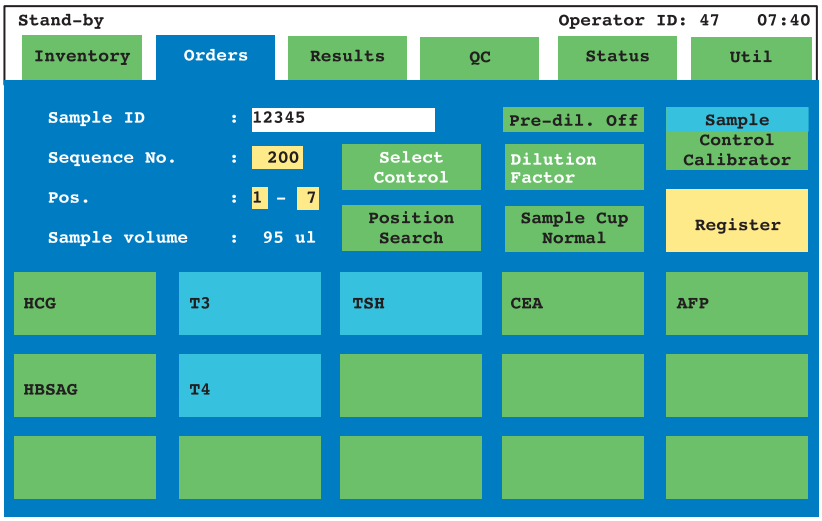
Patient Programming for Non-Interfaced, Bar-Coded Samples

Follow the instructions below to program samples when your laboratory is not interfaced with a host computer and you are using bar-coded samples.

STEP	ACTION
1	Place the bar-coded samples on the sample disk. Make sure the bar codes are facing out so the bar code reader scans them properly.  **Load bar-coded samples**
2	Place a Stop bar code in the next open position on the disk. *If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.* *If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.*

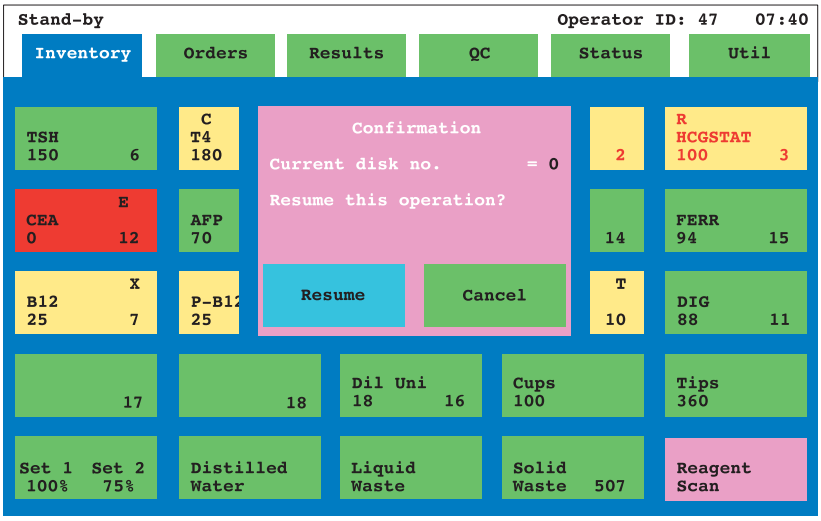
2.8 Routine Sample Measurements – Disk System

STEP	ACTION
3	Touch Status to access the STATUS screen. 
4	Touch Sample Scan to initiate a sample scan. If running in the multiple disk mode, the following screen appears. Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press Resume. If the disk number is incorrect, press Cancel and enter the correct disk number on the STATUS screen. The correct disk number must be selected for the samples to be processed. 

STEP	ACTION
5	When the analyzer returns to Stand-by touch Orders. The first sample scanned is displayed.
6	Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected. 
7	Touch the Sample Cup Normal button to toggle to “Reduced” to utilize reduced dead volume, if necessary. “Reduced” is only for a cup on the sample disk or on top of a tube.
8	Touch Register to register test selections. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • The next available sample position requiring test selections is displayed.
9	Repeat steps 6 - 8 until all samples are programmed.

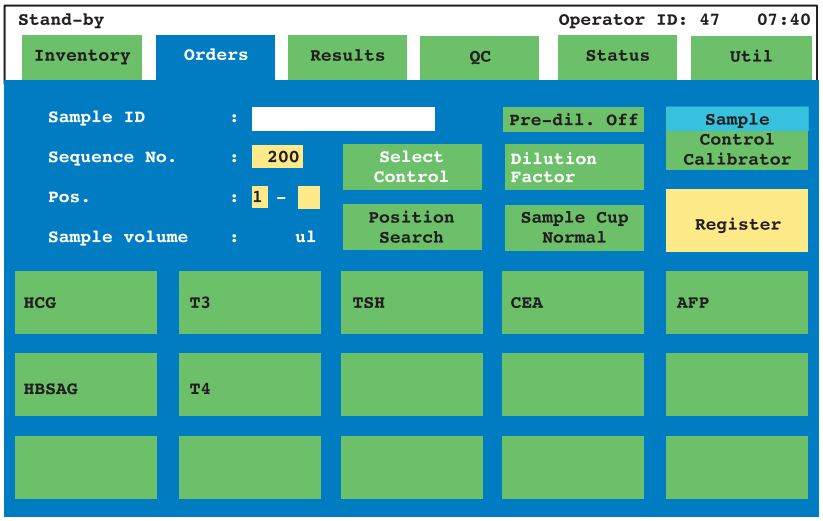
2.8 Routine Sample Measurements – Disk System

STEP	ACTION
10	Press (Start) to start processing samples. If running in the multiple disk mode, the following screen appears. Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press Resume. If the disk number is incorrect, press Cancel and enter the correct disk number on the STATUS screen. The correct disk number must be selected for the samples to be processed.

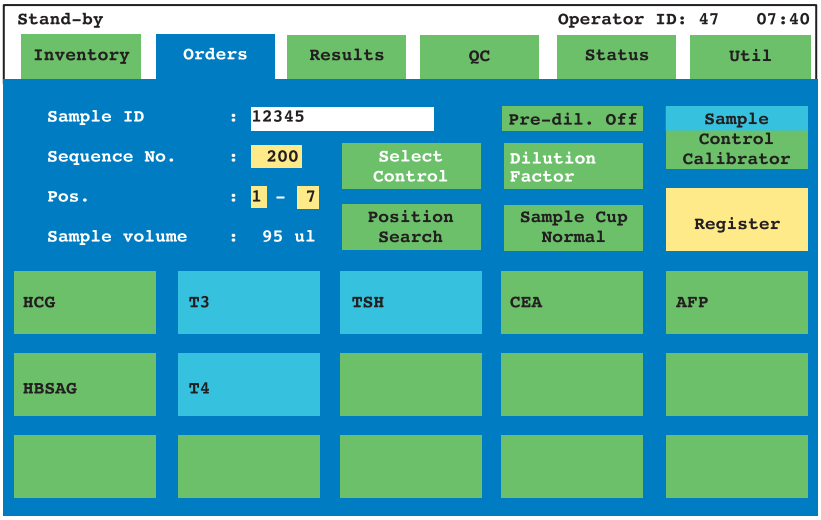


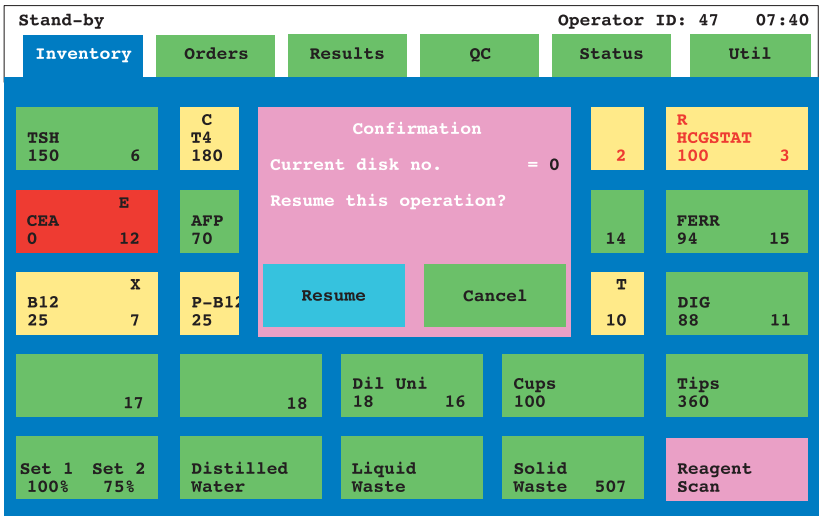
Patient Programming for Non-Interfaced, Non-Bar-Coded Samples

Follow the instructions below to program samples when your laboratory is not interfaced with a host computer and you are using non-bar-coded samples. You can only utilize a numeric sample ID when not using sample bar codes.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	The cursor defaults to the Sample ID field. Type the sample ID of the first sample and press Enter. The sequence number is automatically assigned by the software.
3	The cursor moves to the second Pos. field. Type the desired sample disk position. Press Enter. Place the sample at the designated position on the disk.
4	If running in the multiple disk mode, touch the first disk Pos. field. Type a disk number (0-9) and press Enter.

2.8 Routine Sample Measurements – Disk System

STEP	ACTION
5	Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected. 
6	Touch the Sample Cup Normal button to toggle to “Reduced” to utilize reduced dead volume, if necessary. “Reduced” is only for a cup on the sample disk or on top of a tube.
7	Touch Register to register test selections. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • The next available sample position is displayed.
8	Repeat steps 2 - 7 until all samples are programmed.
9	Place a Stop bar code in the next open position on the disk. *If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.* *If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.*
10	Press Doc to print a worklist (optional).

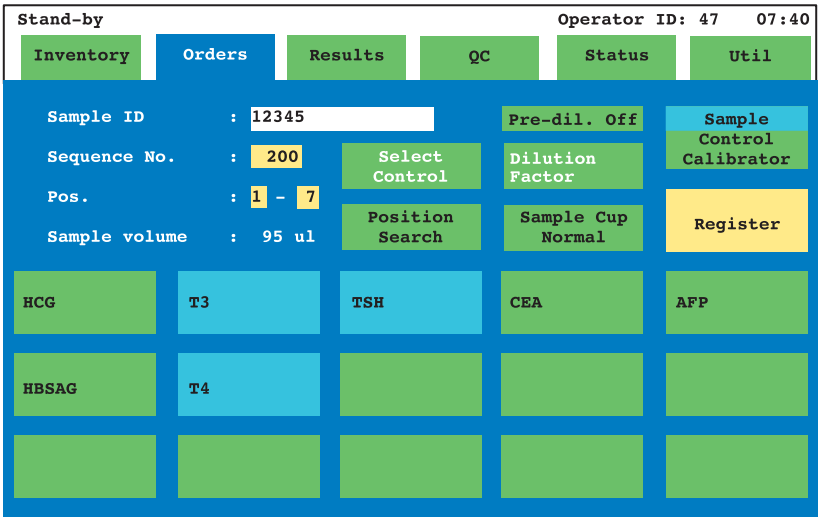
STEP	ACTION
11	Press (Start) to start processing samples. If running in the multiple disk mode, the following screen appears. Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press Resume. If the disk number is incorrect, press Cancel and enter the correct disk number on the STATUS screen. The correct disk number must be selected for the samples to be processed. 

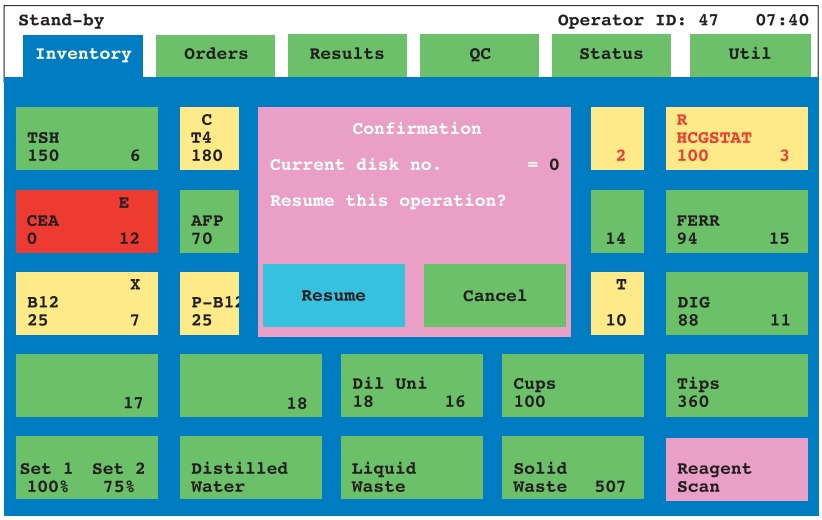
2.8 Routine Sample Measurements – Disk System

Patient Programming for Interfaced, Non-Bar-Coded Samples

Follow the instructions below to program samples when your laboratory is interfaced with a host computer and you are using non-bar-coded samples.

For BATCH downloads:

STEP	ACTION
1	Perform sample programming at the host, if necessary.
2	Download sample IDs, test selections, disk number and position to the analyzer from your host computer. A sequence number is assigned to each sample ID during the download.
3	Touch Orders to access the ORDERS screen. 
4	Print a work list by pressing Doc.
5	Load samples on the sample disk according to the work list.
6	Place a Stop bar code in the next open position on the disk. *If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.* *If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.*

STEP	ACTION
7	Press Start to start processing samples. If running in the multiple disk mode, the following screen appears. Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press Resume. If the disk number is incorrect, press Cancel and enter the correct disk number on the STATUS screen. The correct disk number must be selected for the samples to be processed. 

What's Next?

After sample measurements are complete, proceed to the Section 2.16, Results. If you wish to track samples, add patients during routine operation or process a STAT patient sample, then proceed to one of the following sections:

- 2.10 - Sample Tracking – Disk System
- 2.12 - Measurement of Additional Routine Samples
- 2.14 - STAT Test Selections – Disk System.

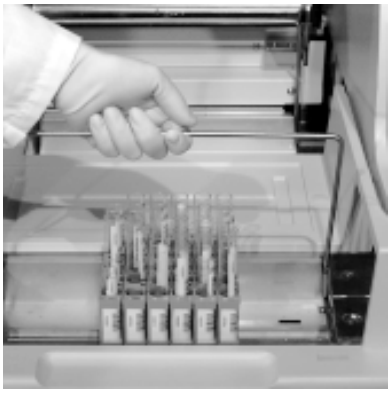
2.9 Routine Sample Measurements – Rack System

Introduction

Patient test selections can be made at any time during operation.

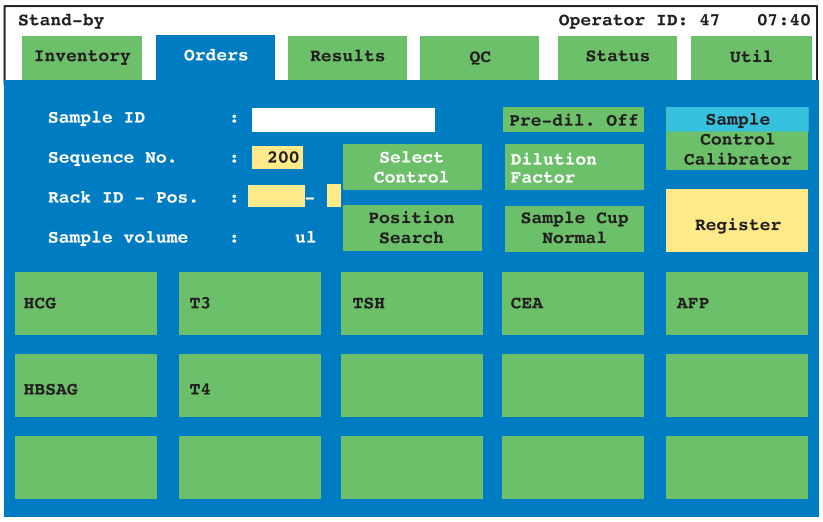
Patient Programming for Interfaced, Bar-Coded Samples

Follow the instructions below to program samples when your laboratory is interfaced with a host computer and you are using bar-coded samples.

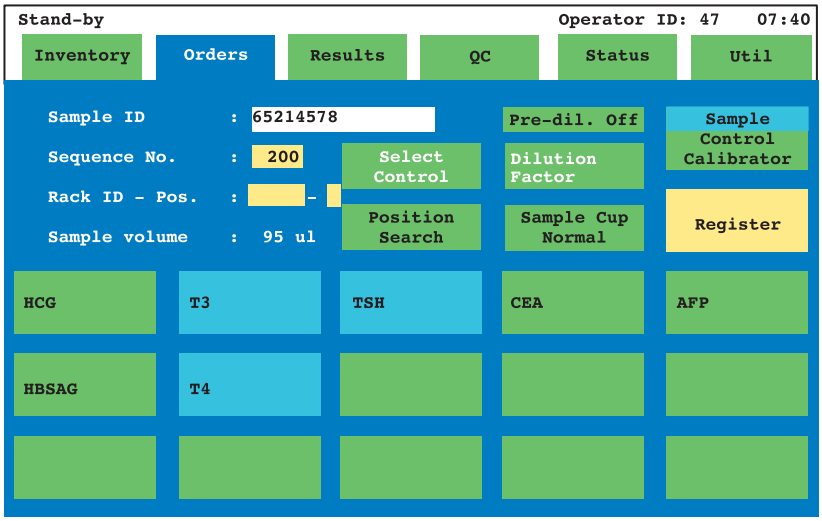
STEP	ACTION
1	Perform sample programming at the host, if necessary.
2	Place the bar-coded samples on the sample racks. Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.
3	Load the racks on a tray and place the tray on the A-Line. At the same time, verify there is a tray on the C-Line.  **Load bar-coded samples on the A-Line**
4	Press (Start) to begin processing samples. As each bar code is scanned the Elecsys queries the host and receives test requests for the sample. The sequence number, rack ID and rack position are automatically assigned during this process.

Patient Programming for Non-Interfaced, Bar-Coded Samples

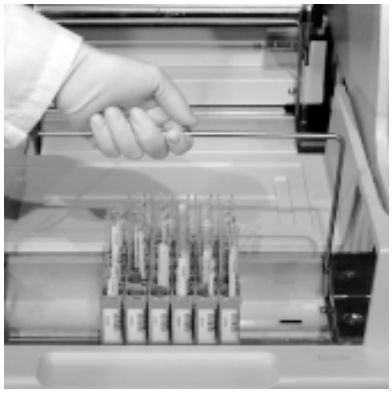
Follow the instructions below to program samples when your laboratory is not interfaced with a host computer and you are using bar-coded samples. You can only utilize a numeric sample ID when not using a host computer. This is because you cannot perform a sample scan (as on the Disk system); all sample ID numbers must be entered manually.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	Touch the Sample ID field. Type the sample ID number of the first sample. Press Enter.

2.9 Routine Sample Measurements – Rack System

STEP	ACTION
3	Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected. 
4	Touch the Sample Cup Normal button to toggle to “Reduced” to utilize reduced dead volume, if necessary. “Reduced” is only for a cup on the sample rack or on top of a tube.
5	Touch Register to register test selections. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • For rack positions 1 - 4, the Rack Pos. increments by one. For position 5, the Rack Pos. returns to 1. • For rack positions 1 - 4, the Rack ID remains unchanged. For position 5, the Rack ID clears.
6	Repeat steps 2 - 5 until all samples are programmed.
7	Place the bar-coded samples on the sample racks. Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.

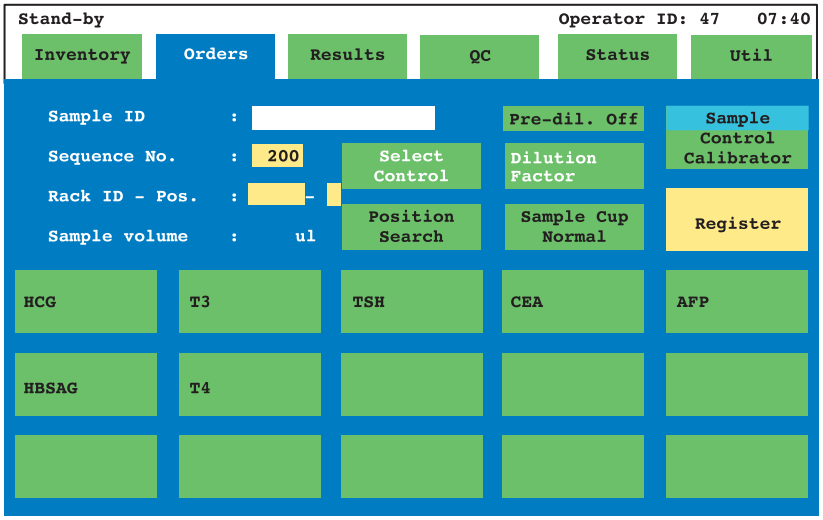
2.9 Routine Sample Measurements – Rack System

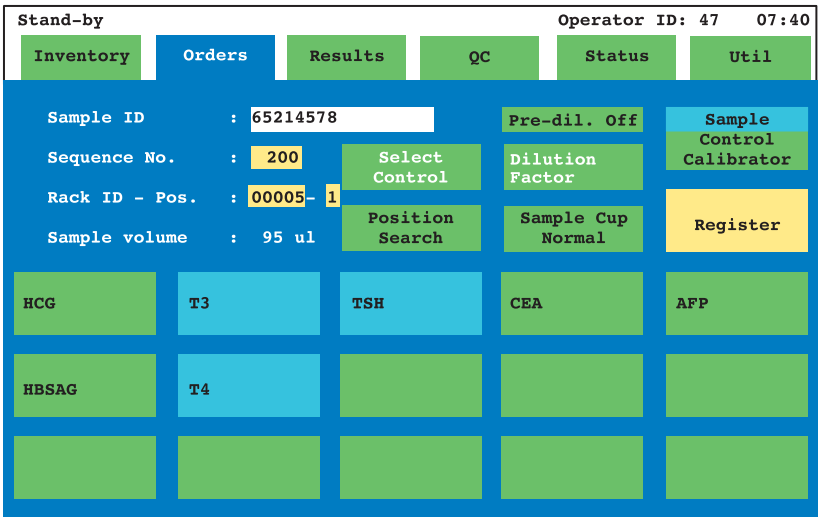
STEP	ACTION
8	Load the racks on a tray and place the tray on the A-Line. At the same time, verify there is a tray on the C-Line.  **Load bar-coded samples on the A-Line**
9	Press (Start) to begin processing samples. As each bar code is scanned the rack ID and rack position are automatically assigned during this process.

2.9 Routine Sample Measurements – Rack System

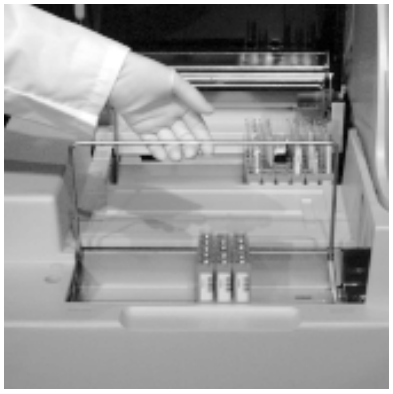
Patient Programming for Non-Interfaced, Non-Bar-Coded Samples

Follow the instructions below to program samples when your laboratory is not interfaced with a host computer and you are using non-bar-coded samples (e.g., sample cups). You can only utilize a numeric sample ID when not using a host computer.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	The cursor defaults to the Sample ID field. Type the sample ID of the first sample and press Enter. The sequence number is automatically assigned by the software.
3	The cursor moves to the Rack Pos. field. Type the rack position and press Enter.
4	Touch the Rack ID field. Type the rack ID number and press Enter. Place the sample at the designated position on the rack.

STEP	ACTION
5	Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected. 
6	Touch the Sample Cup Normal button to toggle to “Reduced” to utilize reduced dead volume, if necessary. “Reduced” is only for a cup on the sample rack or on top of a tube.
7	Touch Register to register test selections. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • For rack positions 1 - 4, the Rack Pos. increments by one. For position 5, the Rack Pos. returns to 1. • For rack positions 1 - 4, the Rack ID remains unchanged. For position 5, the Rack ID clears.
8	Repeat steps 2 - 6 until all samples are programmed.
9	Press Doc to print a work list (optional).

2.9 Routine Sample Measurements – Rack System

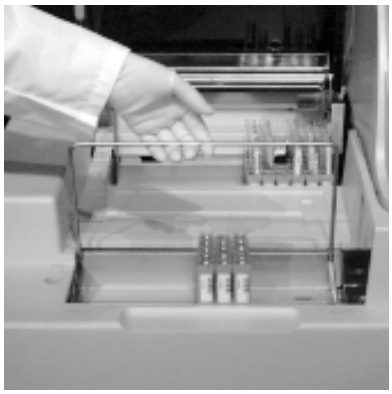
STEP	ACTION
10	Load the racks on a tray and place the tray on the A-Line. At the same time, verify there is a tray on the C-Line.  **Load samples on the A-Line**
11	Press (Start) to begin processing samples.

2.9 Routine Sample Measurements – Rack System

Patient Programming for Interfaced, Non-Bar-Coded Samples

Follow the instructions below to program patient samples when your laboratory is interfaced with a host computer and you are using non-bar-coded samples.

For REAL-TIME queries:

STEP	ACTION
1	Perform sample programming at the host, if necessary. Make sure to program the rack ID and position number at the host.
2	Print a work list at the host.
3	Load non-bar-coded samples on the sample racks according to the host work list.
4	Load the racks on a tray and place the tray on the A-Line. At the same time, verify there is a tray on the C-Line.  **Load samples on the A-Line**
5	Press Start to begin processing samples. As each rack position is encountered, the host is queried to download the sample ID and test selections to the analyzer.

2.9 Routine Sample Measurements – Rack System

What's Next?

After sample measurements are complete, proceed to Section 2.16, Results. If you wish to track samples, add patients during routine operation or process a STAT patient sample, then proceed to one of the following sections:

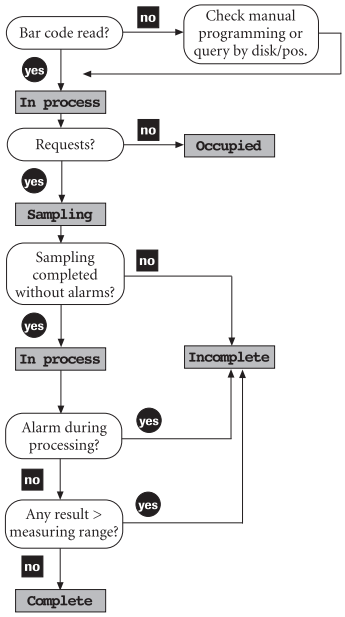
- 2.11 - Sample Tracking – Rack System
- 2.12 - Measurement of Additional Routine Samples
- 2.15 - STAT Test Selections – Rack System.

2.10 Sample Tracking – Disk System

Introduction

Use the STATUS screen to monitor the progress through sample processing. Information about any sample currently on the sample disk is displayed on the screen.

Thirty positions are listed on the screen, each representing the corresponding position on the selected sample disk. Each position lists a status, as well as the position number. The graphic to the right shows an example status flow on the screen. Sample disk status conditions are as follows:



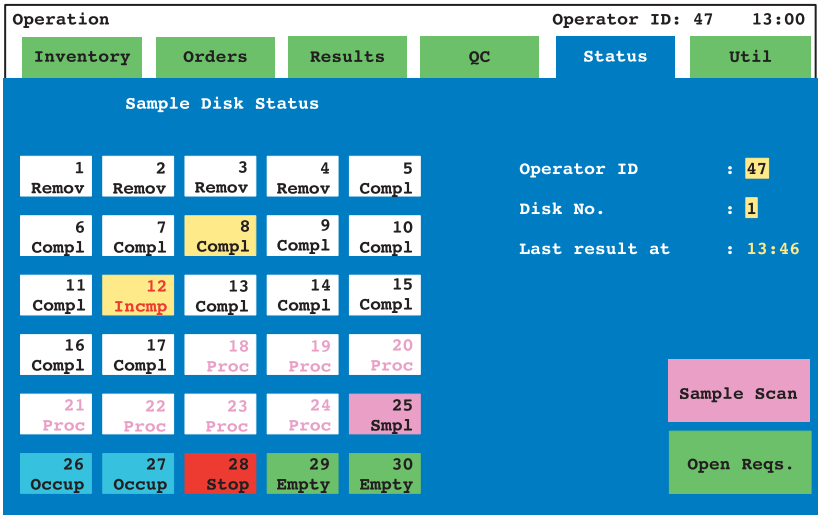
- `Compl` indicates the sample can be removed from the disk (not for calibrators).
- `Remov` indicates the calibrator pipetting is complete and the calibrator can be removed from the disk (not for samples or controls).
- `Empty` indicates that the position is empty and is ready for a sample.
- `Occup` indicates that the sample disk position is assigned or empty (i.e., during a sample scan, the bar code reader cannot distinguish between a cup on the disk or an empty position).
- `Smpl` indicates that the sample is currently being pipetted.
- `Proc` indicates that the sample is in process (i.e., all assays have been pipetted), but results are not ready.
- `Incmp` indicates that there was an error during processing, or the sample has a result greater than the measuring range (not for calibrators).
- `Stop` the stop bar code was scanned.

Sample positions that contain a STAT appear yellow throughout operation, even though their actual status changes.

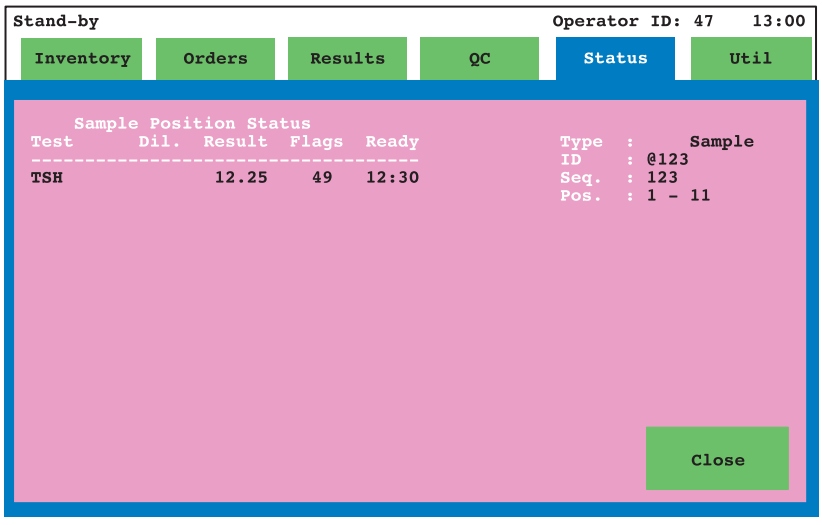
2.10 Sample Tracking – Disk System

Procedure

To review the status of a sample on the disk system, simply touch Status to access the STATUS screen. Identify the position number of the sample in question and read the information on the button.



To obtain more detailed information on the status of a specific position, touch the appropriate button to access the 'Sample Position Status' pop-up window. Refer to the window below.



'Sample Position Status' pop-up window

2.11 Sample Tracking – Rack System

Introduction

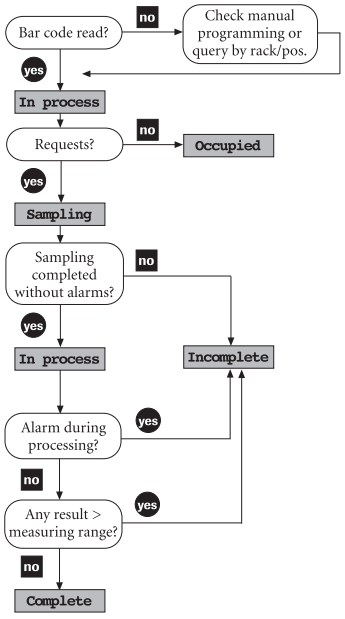
Use the STATUS screen to monitor the progress through sample processing. Information about any sample currently in the output buffer or on the C-Line is displayed on one of four STATUS screens.

When you access STATUS screen from any other screen in the software, Tray part 1 (screen 2) is the screen that appears. Press ▲ Prev to view the Buffer screen (screen 1).

Use Next ▼ and ▲ Prev to move back and forth between the four STATUS screens.

Thirty positions (six rows) are listed on the screen, each row representing a sample rack. To the right of each row is the rack ID number. The upper right corner of each button corresponds to a position on the sample rack. Each position also lists a status. The graphic to the right shows an example status flow on the screen. Sample rack status conditions are as follows:

- `Compl` indicates the sample pipetting is complete and the sample can be removed from the rack on the C-Line.
- `Empty` indicates that the rack position is empty.
- `Occup` indicates that the sample rack position is occupied, but not sampled.
- `Smpl` indicates that the sample is currently being pipetted. This status only appears in row 1, screen 1 (Output Buffer).
- `Proc` indicates that the sample is in process (i.e., all assays have been pipetted), but the results are not ready.
- `Incmp` indicates that there was an error during processing, or the sample has a result greater than the measuring range (not for calibrators).

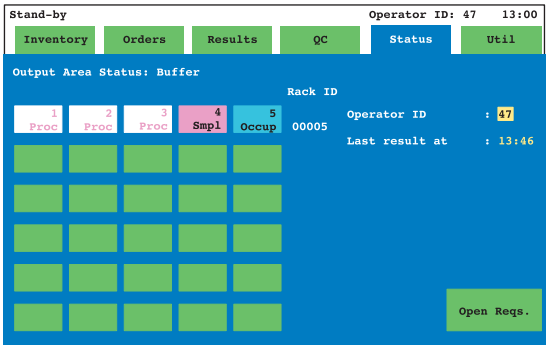


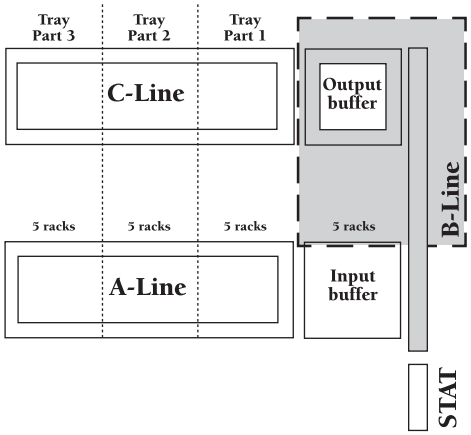
Sample positions that contain a STAT appear yellow throughout operation, even though their actual status changes.

2.11 Sample Tracking – Rack System

The graphics below show how each of the four screens relates to rack position.

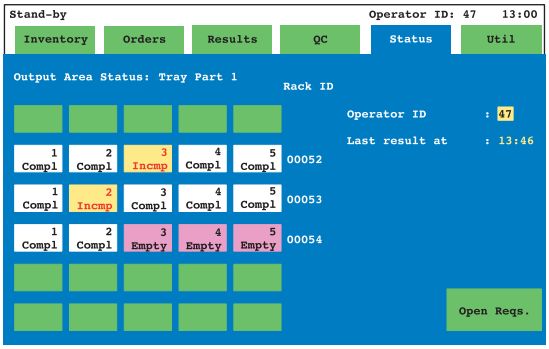
Screen 1 = Output Buffer

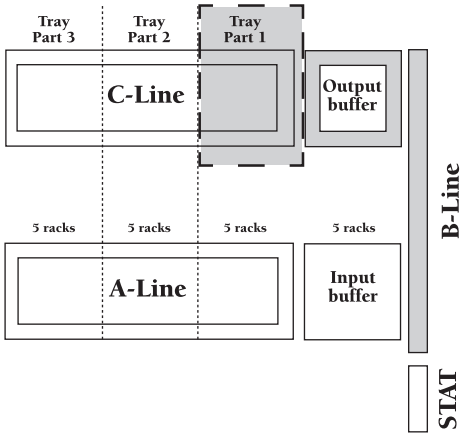




The rack currently being processed on the B-Line appears on screen 1, row 1. Usually only the rack being processed appears here. However, if the C-Line tray is full or missing, then the completed racks in the output buffer will also appear on this screen.

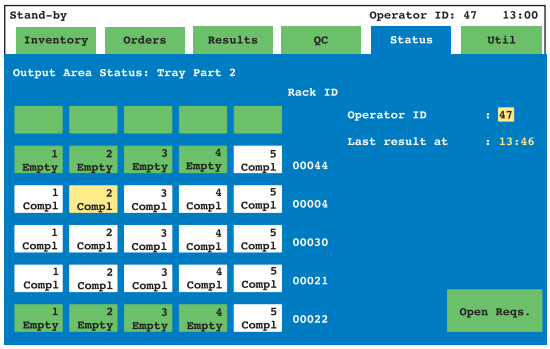
Screen 2 = Tray part 1

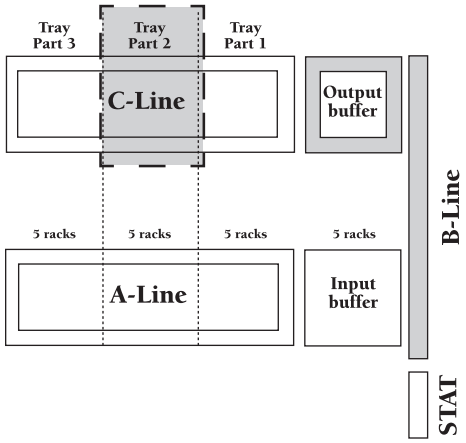




Screen 2 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. The screen updates from top to bottom (i.e., the rack that was processed first appears in row 2 and continues down to row 6. When the next rack is processed, this rack moves from screen 2, row 6 to screen 3, row 2). Therefore, as more racks are processed, they move into tray part 2.

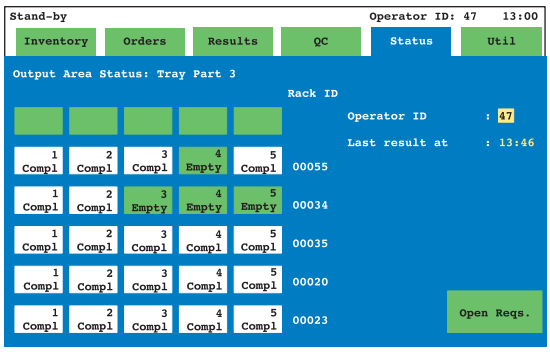
Screen 3 = Tray part 2

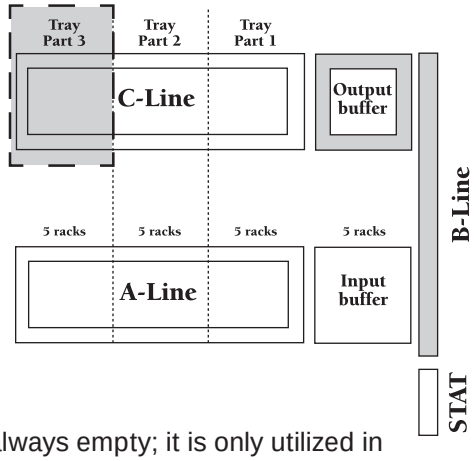




Screen 3 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. Like screen 2, screen 3 updates from top to bottom. When all five rows are full, screen 3, row 6 moves to screen 4, row 2. Therefore, as more racks are processed, they move into tray part 3.

Screen 4 = Tray part 3





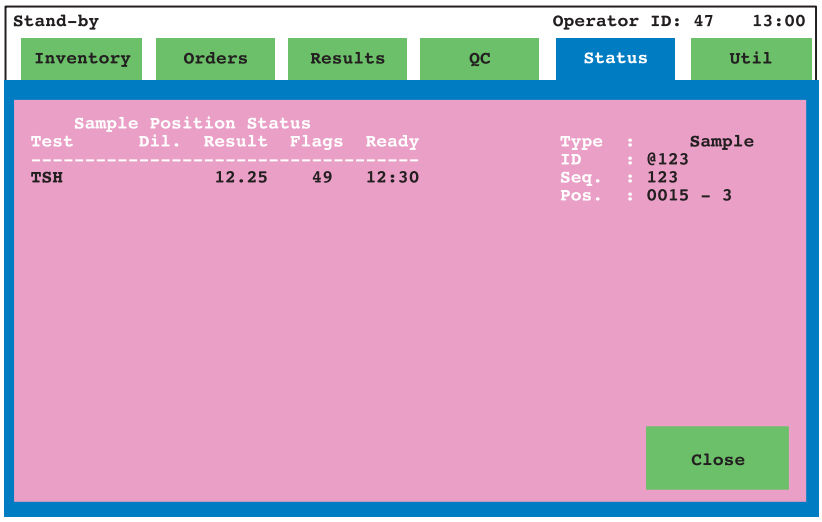
Screen 4 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. Like screens 2 and 3, screen 4 updates from top to bottom. When all five rows are full, screen 4, row 6 displays the first rack processed. When the entire output tray of the C-Line is full, the racks then fill the output buffer. The analyzer displays alarm 63-02-02 (C-Line tray is full). When the C-Line and output buffer are completely filled, the analyzer displays alarm 62-02-04 (C-Line and buffer full).

When you remove the output tray from the C-Line, all the information on the status screen disappears. Deleting open requisitions accomplishes the same task.

2.11 Sample Tracking – Rack System

The STATUS screen may not clear immediately after removing the tray from the C-Line. It may not clear until Start *is next pressed.*

To obtain more detailed information on the status of a specific rack ID and position, touch the appropriate button to access the 'Sample Position Status' pop-up window. Refer to the window below.



'Sample Position Status' pop-up window

2.12 Measurement of Additional Routine Samples

Introduction

The procedure for measuring additional routine samples varies, depending on whether or not you are using bar-coded samples, whether or not your laboratory is interfaced and whether you are running a disk or rack system.

Continuous Loading Using the Single Disk Mode

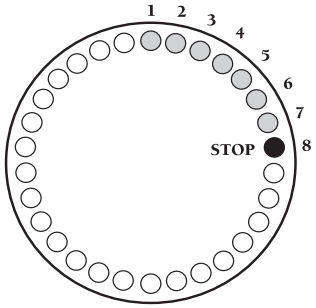
Additional routine samples may be programmed at any time. Follow the appropriate procedure for programming routine samples.

When the analyzer starts from Stand-by, the system always begins at position 1 on the disk and stops at the position of the Stop bar code.

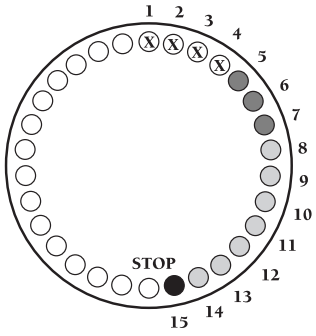
When the analyzer starts from Sampling Stop, the system remembers the last actual position where it was sampling or where the Stop bar code was, and starts at that position. It continues until it reaches the current position of the Stop bar code.

If you forget to place the Stop bar code on the disk, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.

The following example is a graphical representation of continuous loading when utilizing the single disk mode.

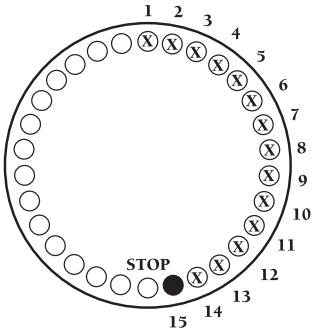


1. Load seven samples on the disk. Place Stop bar code in position 8.

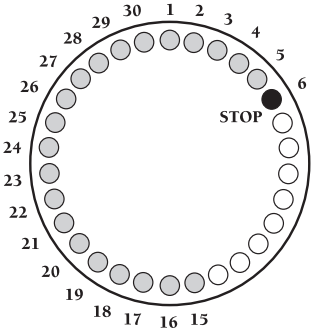


2. When the sample in position 4 is complete, add seven more samples to the disk. Move the Stop bar code to position 15.

2.12 Measurement of Additional Routine Samples



3. All 14 samples are done pipetting. The analyzer goes into Sampling Stop when it reaches the Stop bar code in position 15.



4. Add samples starting at position 15 (i.e., the previous position of the Stop bar code). After pressing Start the system continues sampling past position 30 until it sees the Stop bar code again (here in position 6).

Continuous Loading Using the Multiple Disk Mode

When the analyzer starts from Stand-by, the system always begins at position 1 on the disk and stops at the position of the Stop bar code.

When the analyzer starts from Sampling Stop and there are samples ordered or downloaded for another disk, the system starts with the first sample on the new disk. It continues until it reaches the current position of the Stop bar code.

When the analyzer starts from Sampling Stop after changing the disk number, the system starts again at position 1.

When the analyzer starts from Sampling Stop, and there are NO samples ordered or downloaded for another disk, the system remembers where the Stop bar code was and starts at that position. It continues until it reaches the current position of the Stop bar code.

If you forget to place the Stop bar code on the disk, the disk stops at position 30.

Continuous Loading Using the Rack System

There are two ways to continuously load on the rack system.

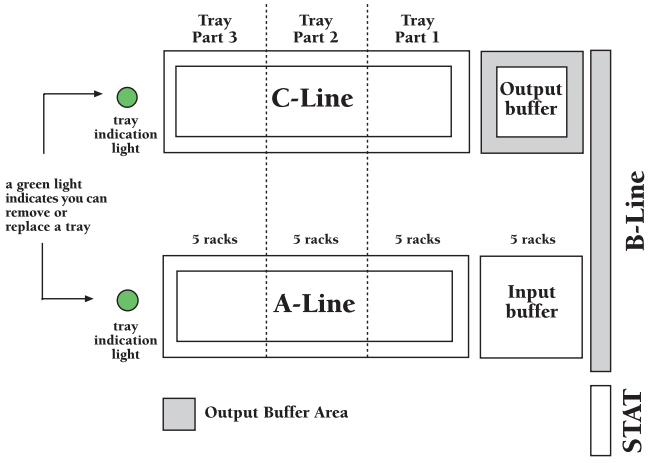
- Add single racks to the A-Line. Refer to the photograph below.

You can only add single racks to the tray when the tray indication light is green. When the light is out, the pusher arm is preparing to move.

Loading a rack on the A-Line during operation

- Add a loaded tray to the A-Line. Refer to the graphic below.

You can only add a tray to the A-Line when the tray indication light is green. When the light is out, the pusher arm is preparing to move.



2.13 Dilutions

Introduction

Sample results that exceed the measuring range of the assay must be diluted. Dilutions can be requested from the ORDERS screen and are performed automatically by the analyzer. Refer to the *Dilution* section of the package insert for recommended dilutions.

The Dilution Factor button is only available for assays that are encoded in the reagent bar code as being able to dilute. For example, you cannot dilute FT3, therefore, you are unable to select automatic dilution on an FT3 sample. Also, the button is only available when a bottle of Diluent Universal is on the analyzer.

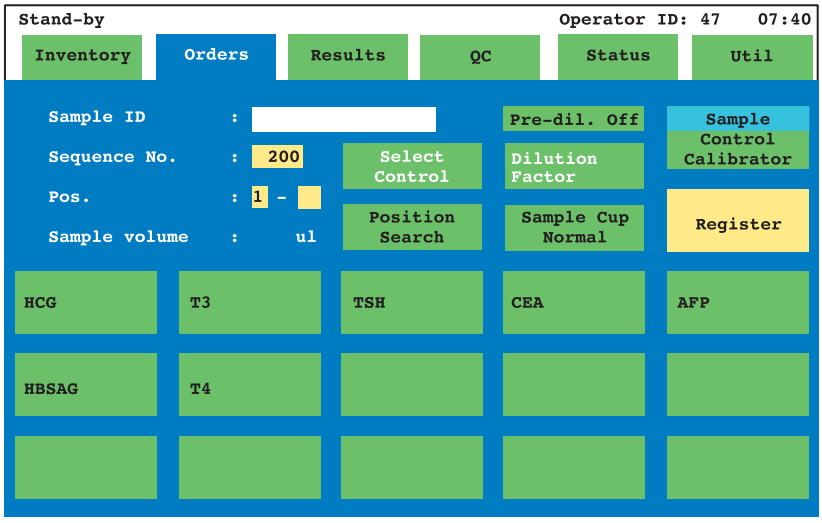
The measuring range is recalculated based on the selected dilution factor. The resulting diluted sample result is not inappropriately flagged as outside the measuring range.

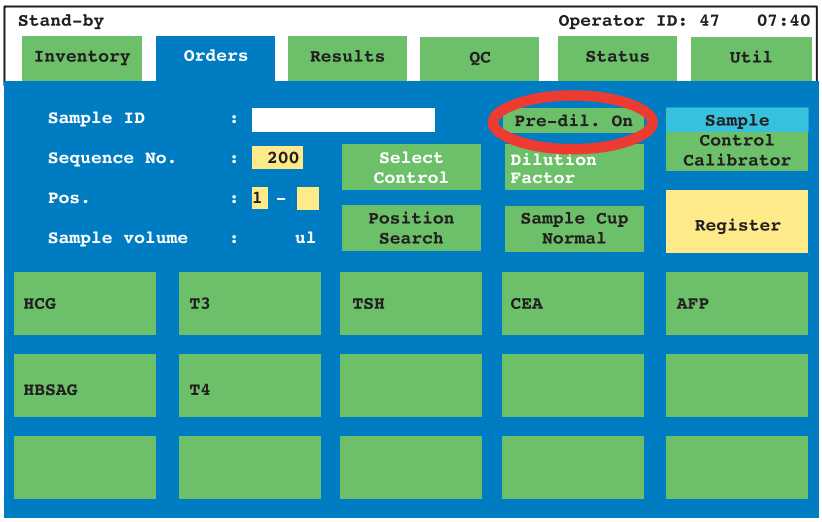
For additional information on dilutions, refer to Chapter 3, Mechanical Theory – *Reference Guide* or Chapter 3, Orders – *Software Guide*.

Predilution of Samples

You can predilute samples and have the analyzer flag them on reports and on the RESULTS screen. The ensuing results are NOT corrected for any dilution factor. It is the operator's responsibility to calculate the final result. Follow the instructions below to flag a sample as prediluted. The process is the same for both disk and rack systems. This illustration utilizes screens from a disk system.

STEP	ACTION
1	Touch Orders to access the ORDERS screen.

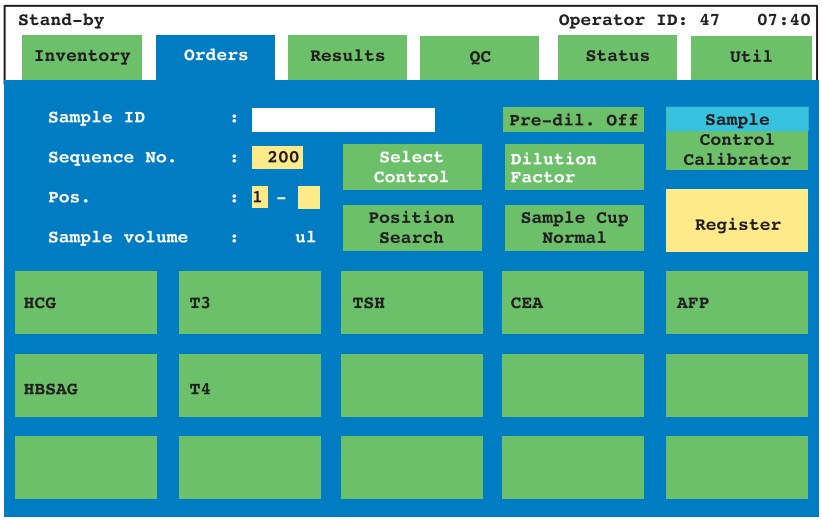


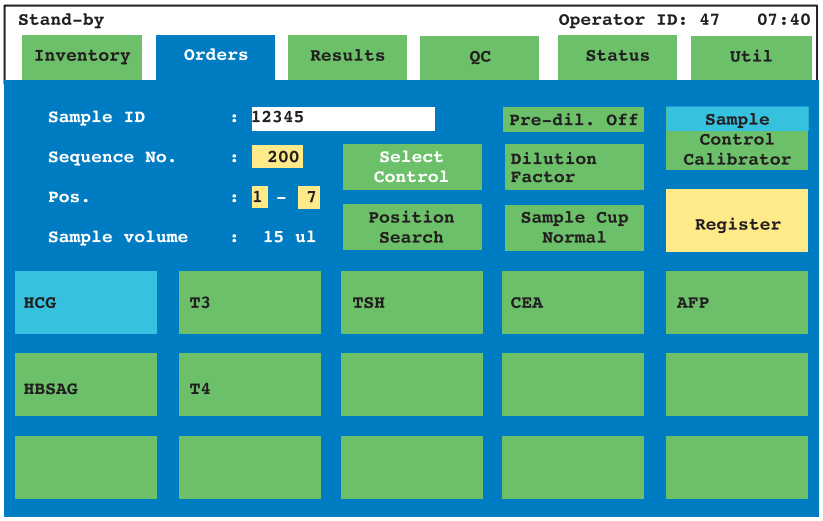
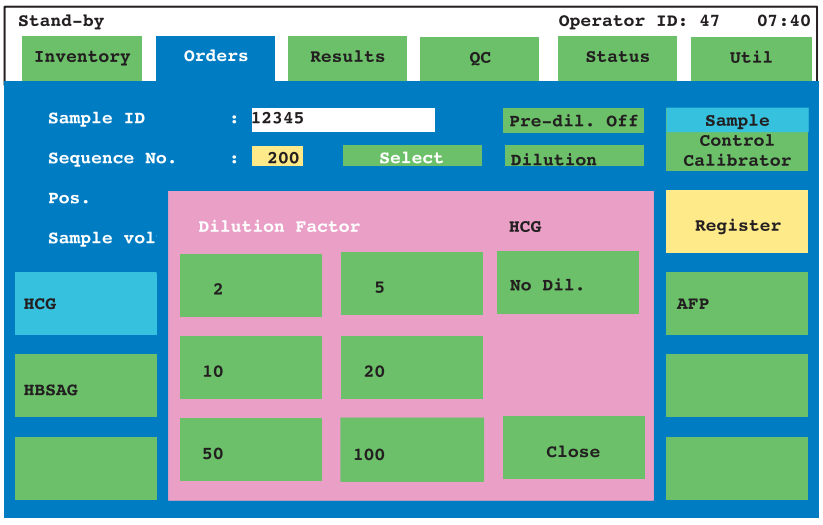
STEP	ACTION
2	Touch the Pre-dil. Off button to toggle to the “On” choice. 
3	Program your sample as you would normally. Refer to Section 2.8, Routine Sample Measurements – Disk System or Section 2.9, Routine Sample Measurements – Rack System for details.
4	Touch Register when complete.
5	Press Start to begin processing samples. A “P” prints on the Results reports. Refer to Section 8.7, Results reports – *Software Guide*.

2.13 Dilutions

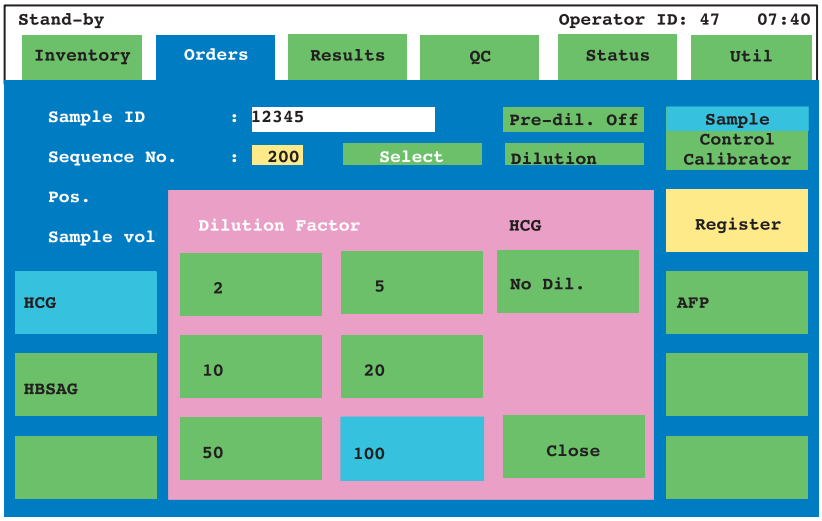
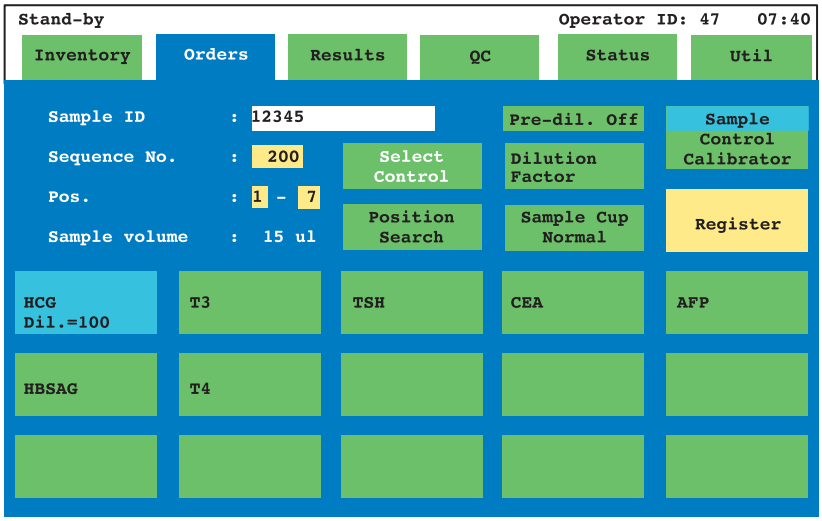
Procedure for Automatic Dilution by the Analyzer

Follow the instructions below to dilute a patient sample. The process is the same for both disk and rack systems. The only difference is in the appearance of the Position fields on the ORDERS screen. This illustration utilizes screens from a disk system. Rack differences are noted accordingly.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	Touch the Sample ID field and type the ID (numeric only) of the sample to be diluted. Press Enter.
3	*On the disk system:* the cursor automatically moves to the second Pos. field. Type the sample disk position. Press Enter. Proceed to step 5. *On the rack system:* the cursor automatically moves to the Rack Pos. field. Type the position number and press Enter.
4	*On the rack system:* touch the Rack ID field. Type the rack ID and press Enter.

STEP	ACTION
5	Touch the test button of the assay that requires dilution. The test button color changes to light blue. At the same time, the text on the Dilution Factor button turns black, indicating that the 'Dilution Factor' pop-up window is available. 
6	Touch Dilution Factor. The 'Dilution Factor' pop-up window appears. 

2.13 Dilutions

STEP	ACTION
7	Touch the appropriate dilution factor. Refer to the package insert for the recommended dilutions. 
8	Touch Close. The 'Dilution Factor' pop-up window closes.  *Closing the window without selecting a dilution factor or selecting "no dilution" results in the sample being performed without a dilution.*

STEP	ACTION
9	Touch Register to register the dilution test selection.
10	Press Start to initiate operation. The sample is automatically diluted by the 2010 analyzer. When calculating the final sample concentration, the software calculates the result based on the selected dilution factor.

2.14 STAT Test Selections – Disk System

Introduction

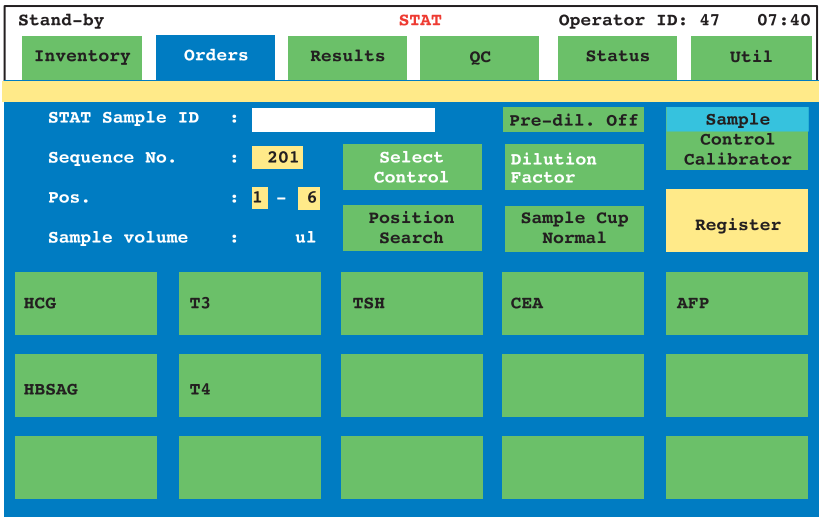
STAT patient test selections can be made when the instrument is in Operation, S. Stop, Stand-by or Stop.

During STAT processing, the current sample finishes pipetting. The STAT samples are pipetted next. When the STAT sampling is complete, the analyzer proceeds to the next sample (i.e., the sample directly after where it had previously stopped) and resumes pipetting routine samples.

STAT Patient Programming for Interfaced, Bar-Coded Samples

In the STAT mode, when the ORDERS screen is accessed an available disk position is suggested by the software. You can override the system's suggested position.

Test selections must be made at the host system prior to sample query from the analyzer.

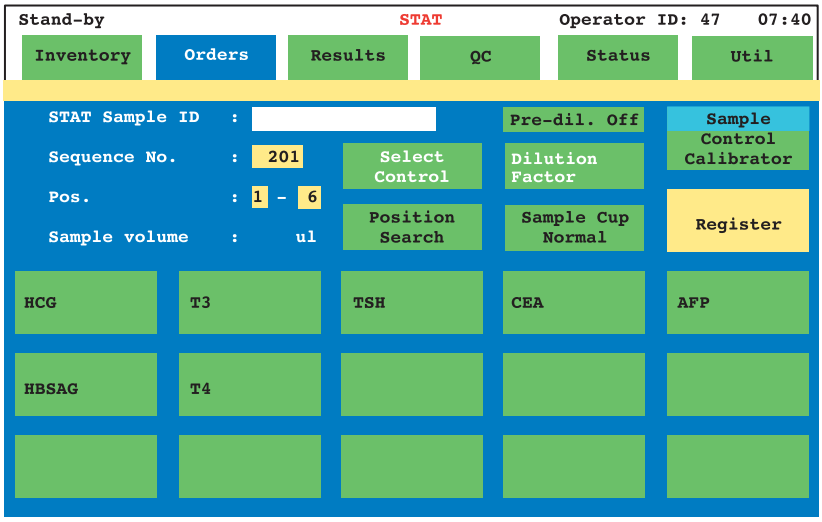
STEP	ACTION
1	Press *Stat.
2	Touch Orders to access the ORDERS screen. 
3	Load the STAT sample in the suggested disk position or a different open position on the sample disk. If you change the disk position, you must press Enter and Register before proceeding.

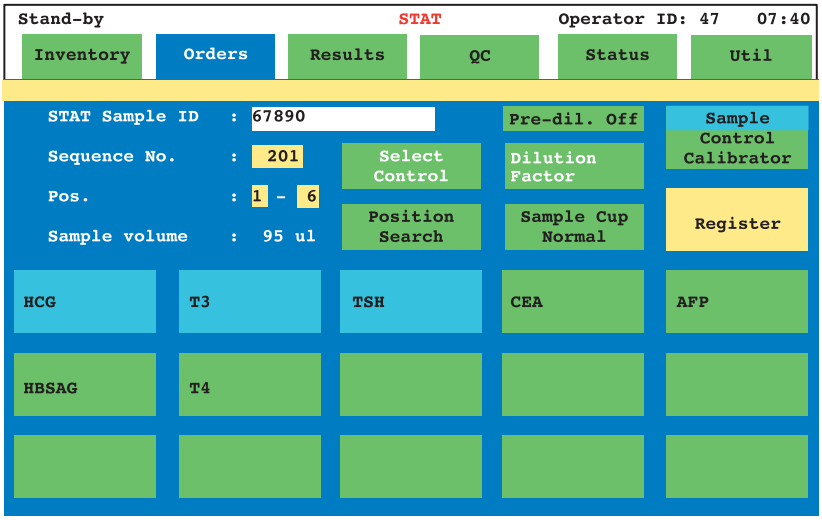
STEP	ACTION
4	If in **Stand-by** or **S. Stop**, press (Start) to resume operation. If in **Operation** or **Initialization**, the registered STAT sample is the next sample pipetted. If in **Finalization**, wait for the analyzer to reach Stand-by, then press (Start).
5	Press (•Stat) to exit the STAT mode.

2.14 STAT Test Selections – Disk System

STAT Patient Programming for Non-Interfaced, Bar-Coded or Non-Bar-Coded Samples

Follow the steps below to order STAT samples when your laboratory is not interfaced with a host computer and you are using either bar-coded or non-bar-coded samples. In the STAT mode, when the ORDERS screen is accessed an available disk position is suggested by the software. You can override the system's suggested position.

STEP	ACTION
1	Press  .
2	Touch Orders to access the ORDERS screen. 
3	Load the STAT sample in the suggested disk position or a different open position on the sample disk. If you change the disk position, you must press Enter before proceeding. If using ***bar-coded*** samples, proceed to step 6.
4	If using ***non-bar-coded*** samples: Touch the STAT Sample ID field, type the sample ID (numeric only) of the sample and press Enter .

STEP	ACTION
5	If running in the multiple disk mode, touch the first Pos. field, type the sample disk number (0-9) and press Enter.
6	Touch the test buttons to select assays. 
7	Touch the Sample Cup Normal button to utilize reduced dead volume, if necessary.
8	Touch Register to register test selections and advance to the next sample.
9	Repeat steps 3 - 8 for all remaining STAT samples.
10	Press Start. If running in the multiple disk mode, touch Resume after verifying the sample disk number.
11	Press Stat to exit the STAT mode.

2.15 STAT Test Selections – Rack System

Introduction

STAT patient test selections can be made when the instrument is in Operation, R. Stop, Stand-by or Stop.

During STAT processing, the current sample rack finishes pipetting. The samples in the STAT rack are pipetted next. When the STAT sampling is complete, the analyzer proceeds to the next rack on the A-Line and resumes pipetting routine samples.

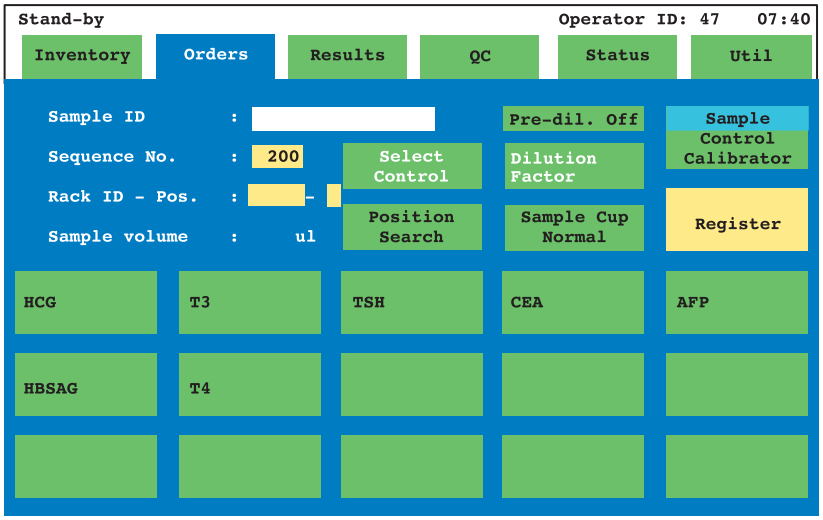
STAT Patient Programming for Interfaced, Bar-Coded Samples

Follow the instructions below to order STAT samples when your laboratory is interfaced with a host computer and you are using bar-coded samples.

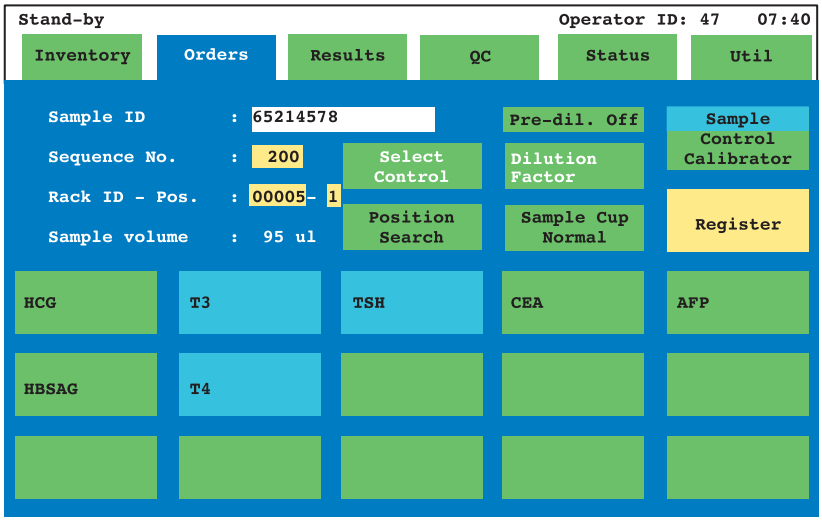
STEP	ACTION
1	Perform sample programming at the host, if necessary.
2	Place the STAT bar-coded samples on a sample rack. Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.
3	Load the rack in the STAT position. *Refer to the label on the STAT position to ensure correct orientation of the rack.*  **Load bar-coded samples at STAT position**
4	Press *Stat to begin processing samples. As each bar code is scanned the Elecsys queries the host and receives test selections for the sample. The sequence number, rack ID and rack position are automatically assigned during this process. *If multiple STAT racks are necessary, you must press *Stat each time a STAT rack is loaded in the STAT position.*

STAT Patient Programming for Non-Interfaced, Bar-Coded and Non-Bar-Coded Samples

Follow the instructions below to order STAT samples when your laboratory is not interfaced with a host computer and you are using bar-coded or non-bar-coded samples. You can only use a numeric sample ID when not using a host computer.

STEP	ACTION
1	Load the sample in the rack. *If using bar-coded samples:* Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.
2	Touch Orders to access the ORDERS screen. 
3	The cursor defaults to the Sample ID field. Type the sample ID number of the first sample. Press Enter. *If using bar-coded samples:* proceed to step 6.
4	*If using non bar-coded samples:* The cursor moves to the Rack Pos. field. Type the rack position (1-5) and press Enter.

2.15 STAT Test Selections – Rack System

STEP	ACTION
5	Touch the Rack ID field. Type the appropriate rack ID number and press Enter. Place the sample at the designated position on the rack.
6	Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected. 
7	Touch the Sample Cup Normal button to toggle to “Reduced” to utilize reduced dead volume, if necessary. “Reduced” is only for a cup on the sample rack or on top of a tube.
8	Touch Register to register test selections. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • For rack positions 1 - 4, the Rack Pos. increments by one. For position 5, the Rack Pos. returns to 1. • For rack positions 1 - 4, the Rack ID remains unchanged. For position 5, the Rack ID clears.
9	Repeat steps 3 - 8 until all STAT samples are programmed.

STEP	ACTION
10	Load the rack in the STAT position. *Refer to the label on the STAT position to ensure correct orientation of the rack.*  **Load bar-coded samples at STAT position**
11	Press *Stat to begin processing samples. *If multiple STAT racks are necessary, you must press *Stat each time a STAT rack is loaded in the STAT position.*

2.15 STAT Test Selections – Rack System

STAT Patient Programming for Interfaced, Non-Bar-Coded Samples

Follow the instructions below to order STAT samples when your laboratory is interfaced with a host computer and you are using non-bar-coded samples.

STEP	ACTION
1	Perform sample programming at the host, if necessary.
2	Print a work list at the host.
3	Load the STAT non-bar-coded sample on the sample rack according to the host work list.
4	Load the rack in the STAT position. *Refer to the label on the STAT position to ensure correct orientation of the rack.*  **Load non-bar-coded samples at STAT position**
5	Press *Stat to begin processing samples. As each STAT position is encountered, the host is queried to download the sample ID and test selections to the analyzer. *If multiple STAT racks are necessary, you must press *Stat each time a STAT rack is loaded in the STAT position.*

Introduction

You can evaluate control and patient results on printed reports or on the RESULTS screen. All samples can be viewed printed or uploaded from the RESULTS screen. The database hold up to 600 results, depending upon the number of orders in the system. Documented results are then overwritten on a first in, first out (FIFO) basis. You can delete documented samples from the database to free up additional space.

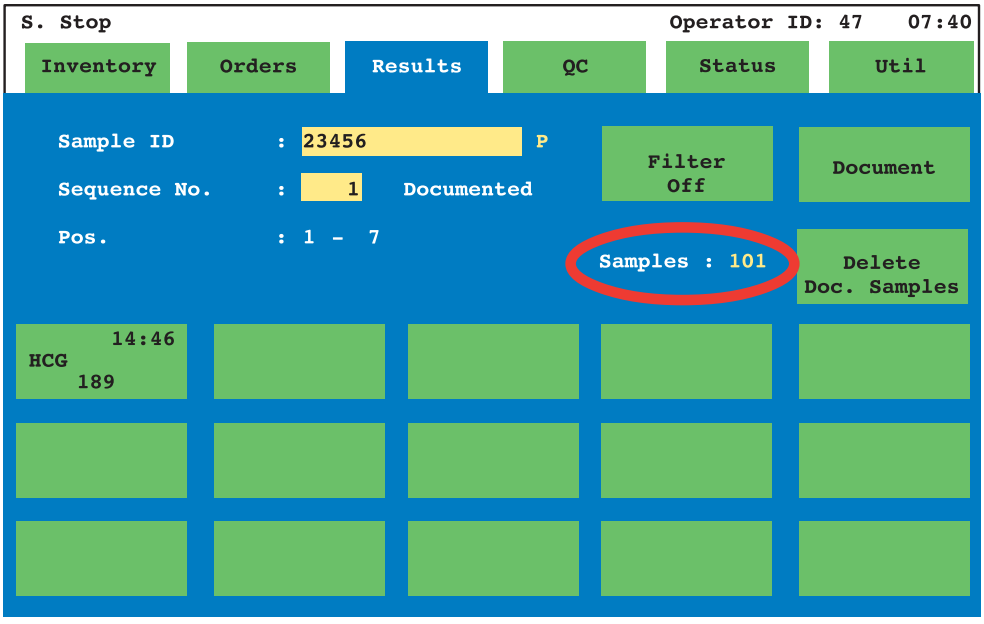
Viewing Patient Results

You can view patient results in the RESULTS screen. As soon as results are printed, uploaded or printed/uploaded, they are considered to be "documented." After documentation, the word "Documented" appears to the right of the sequence number. Partial sample results can be viewed from this screen as soon they are available from the system. The screen updates every 42 seconds.

You can search for information on a patient by touching the `Sequence No.` field and pressing Next ▼ or ▲ Prev until the appropriate patient sample is found.

You can also search for a patient by touching the `Sample ID` field and typing the sample ID (numeric only).

Refer to the example for the disk system below. The only difference in appearance between disk and rack systems is in the `Position` fields.

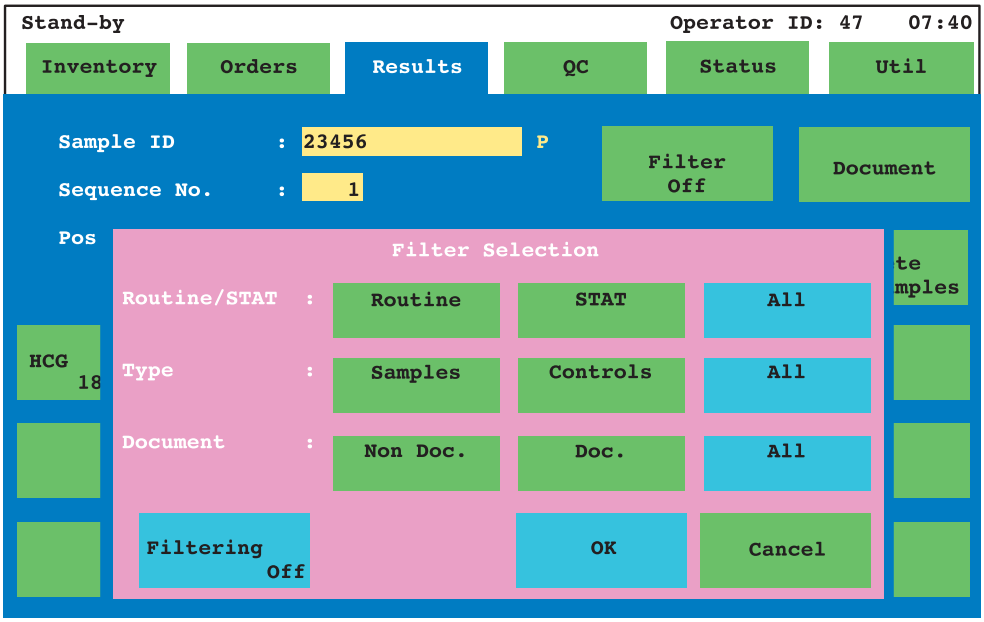


2.16 Results

Filtering Patient Results

You now have the opportunity to filter the type of samples you want to view, document or print. Touch the 

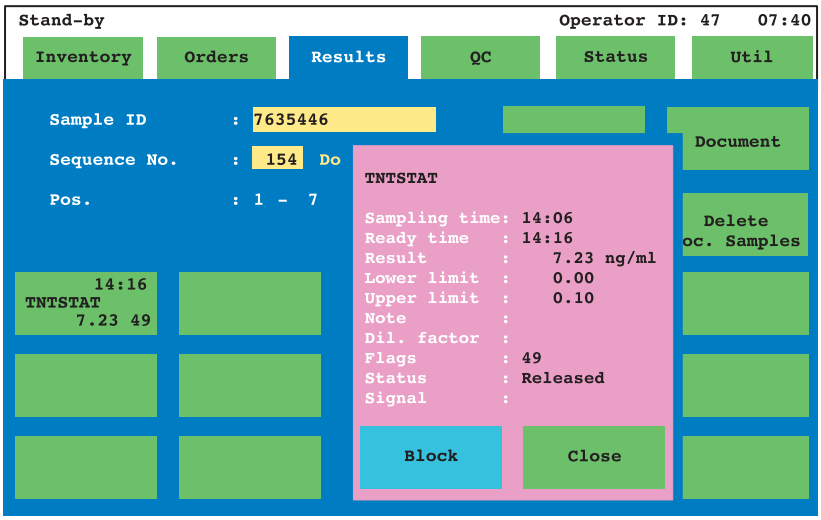
button to access the Filter Selection' pop-up window (as seen below). Here you can activate the filtering feature and select the filter mix you wish to see. The default settings are for Filtering to be "Off" and the choices to be "All." The total number of samples filtered as per the choices appears in the `Samples` field below the button. Refer to the red circle on the previous page.



'Filter Selection' pop-up window

Blocking Patient Results

You have the opportunity to block or release any patient results prior to documenting, but only if automatic options (printing and/or uploading) are OFF. Touch the button of a specific test to view the details of that test such as, expected values, any data flags and release status. Refer to the example below.

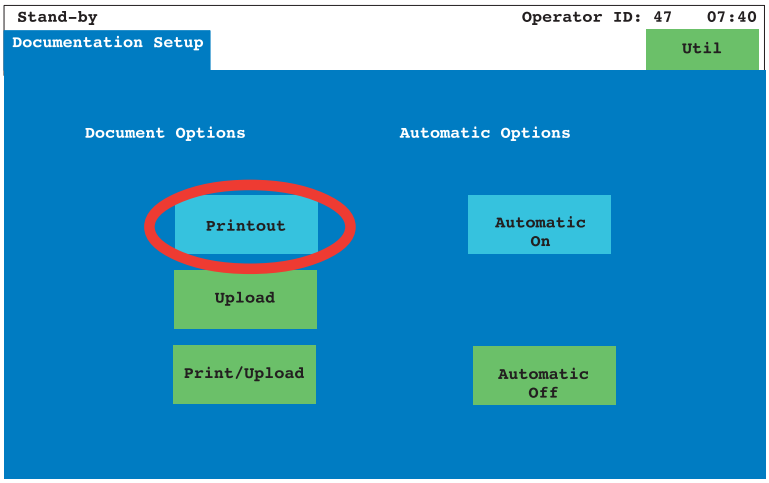


A result can be blocked by touching the Block button. These results are marked “Blocked” on reports and are flagged with a “B” in the data stream that is sent to the host computer when the sample is uploaded.

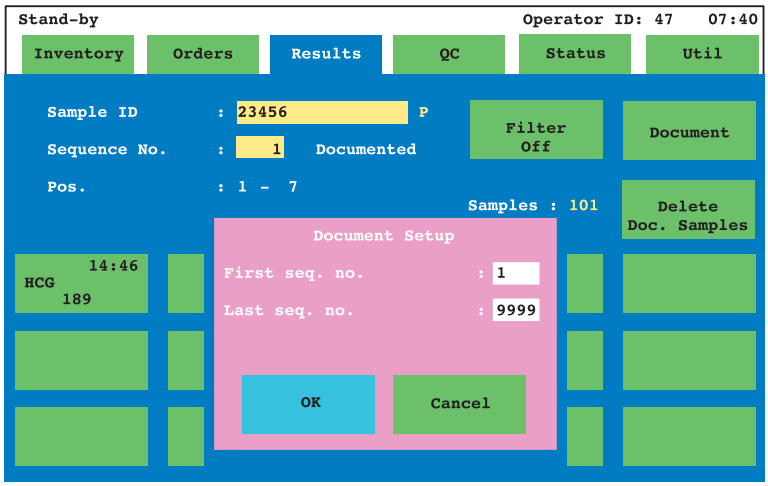
2.16 Results

Document Patient Results by Printing

The DOCUMENTATION SETUP screen allows you to select the desired document option. The option is selected if the button color is light blue. Refer to the screen below.



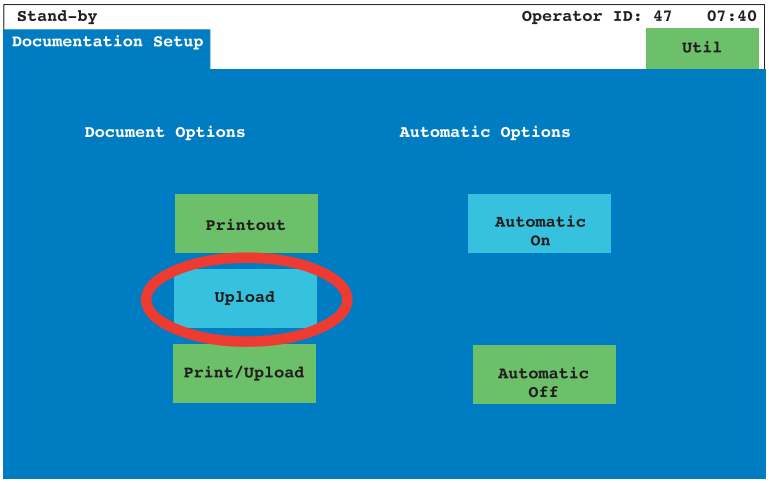
IF the automatic option for printing is...	THEN the results...
ON	print automatically when available.
OFF	can be printed one at a time by pressing Doc in the RESULTS screen. All results can be printed at one time by touching Document from the RESULTS screen and selecting the range of sequence numbers to document. Refer to the screen below.



Document Patient Results by Uploading

The DOCUMENTATION SETUP screen allows you to select the desired document option. Results can be uploaded to the host more than one time, if necessary. The option is selected if the button color is light blue. Refer to the screen below.

If a problem occurs with your host interface, change your document option to "Printout" until the problem is resolved. This allows you to document results and not fill the database. Results can be uploaded at a later time, if necessary, provided they have not been overwritten.



IF the automatic option for uploading is...	THEN the results...
ON	upload automatically to the host when available.
OFF	can be manually uploaded one at a time by pressing Doc in the RESULTS screen. All results can be uploaded at one time by touching Document from the RESULTS screen and selecting the range of sequence numbers to document.

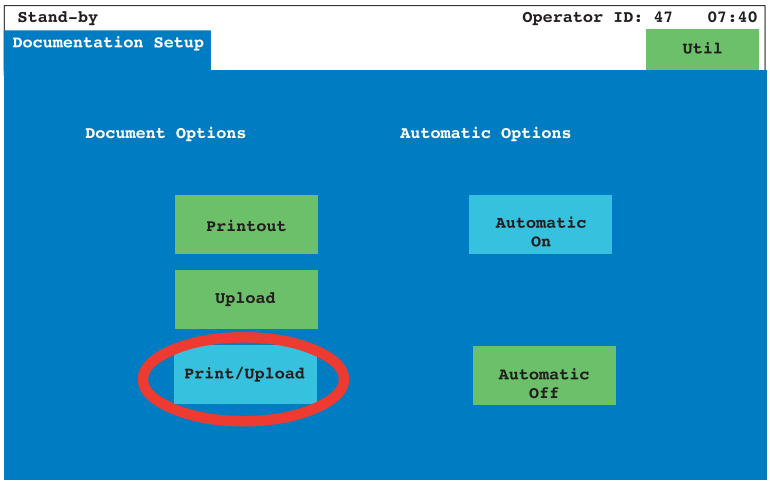
If the host communication is OFF, alarm 44-01-12: Interface off-line appears. You must also change the Document Option to "Printout."

2.16 Results

Document Patient Results by Printing/Uploading

The DOCUMENTATION SETUP screen allows you to select the desired document option. Results can be uploaded to the host more than one time, if necessary. The option is selected if the button color is light blue. Refer to the screen below.

If you select print/upload as your document option, then you must **print AND upload** a result before it is considered documented. To only print or upload these results causes your database to fill and not allow further patient orders. If a problem occurs with your host interface, change your document option to "Printout" until the problem is resolved. This allows you to document results and not fill the database. Results can be uploaded at a later time, if necessary, provided they have not been overwritten.



IF the automatic option for print/upload is...	THEN the results...
ON	print and upload automatically to the host when available.
OFF	can be manually printed and uploaded one at a time by pressing Doc in the RESULTS screen. All results can be print/uploaded at one time by touching Document from the RESULTS screen and selecting the range of sequence numbers to document.

If the host communication is OFF, alarm 44-01-12: Interface off-line appears. You must also change the Document Option to "Printout."

Saving Patient Sample Results

All sample results are saved automatically by the software into instrument memory, as well as on the data disk. The capacity is 600 test records (i.e., orders, tests in process and documented test results). After that number is reached, results are saved in the RESULTS screen on a first in, first out basis (i.e., the oldest sample is overwritten first).

2.17 Post-Operation Data Management

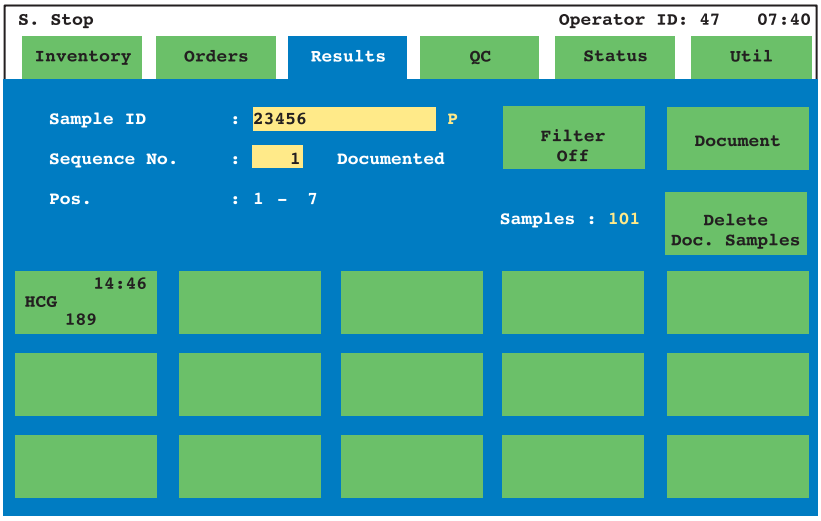
Review Results

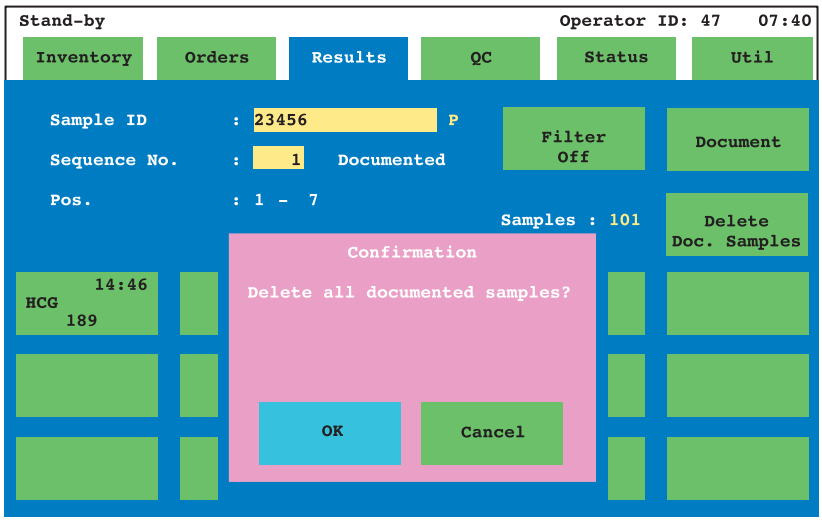
As your results are available, review them. Those with an “Incomplete” status or questionable results should be repeated and/or blocked, as necessary. Block results from the ‘Result Details’ pop-up window. Remember, your automatic options must be OFF to be able to block results.

Delete Documented Samples

When samples are documented, they can be deleted from the database thereby freeing up additional space in the database. Filter settings have no effect on this function. Follow the instructions below to delete documented samples, if necessary.

STEP	ACTION
1	Touch Results to access the STATUS screen.



STEP	ACTION
2	Touch Delete Doc. Samples to access the Delete Documented Samples 'Confirmation' pop-up window. 
3	Touch OK.

2.18 Daily Maintenance

Introduction

Daily maintenance is minimal on the Elecsys 2010 analyzer. At some point during the day clean the S/R probe.

DO NOT clean the mixer. Cleaning the mixer may alter the adjustments and cause movement errors.

Clean the S/R Probe

Operator time: Approximately 1 minute.

Analyzer time: None.

Precautions: The operation switch must be OFF.

Materials required: Gauze squares
Distilled or deionized water
70% isopropyl alcohol

Procedure

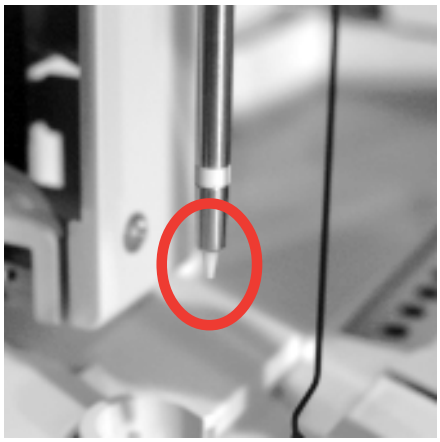
1. Move the S/R probe to an area where you can readily access it.

   Power must be off to move analyzer components. If power is on, the motors are engaged and attempted movement may damage these components.

2. Wipe the outer surfaces of the S/R probe and probe tip with a gauze square soaked in distilled or deionized water.

   Do not bend the probe during cleaning! Be careful to not damage the lower end of the S/R probe. See below.

Wipe S/R probe



S/R probe tip

3. If the probe appears dirty, wipe the outer surfaces with a gauze square soaked in 70% isopropyl alcohol. Follow with a gauze square soaked in distilled or deionized water.
4. When you power ON the analyzer, it performs the start-up reset operation, and each mechanism returns to its home or Stand-by position.

Finalization Maintenance

Finalization is the analyzer status that occurs between the time when the analyzer stops pipetting samples (S. Stop or R. Stop) and Stand-by. Pressing Stop when the analyzer status is S. Stop or R. Stop bypasses finalization and puts the analyzer directly into Stand-by. If the Elecsys 2010 analyzer does not automatically enter finalization status during the course of the day (i.e., continuously loading the analyzer or pressing Stop), you must initiate finalization maintenance.

Finalization allows the analyzer to stand unused for several hours (e.g., overnight). The system is primed with water, the measuring cell is filled with ProCell and the sipper probe is cleaned with water.

Operator time: Approximately 30 seconds.

Analyzer time: Approximately 5 minutes.

Precautions: None.

Materials required: None.

Procedure

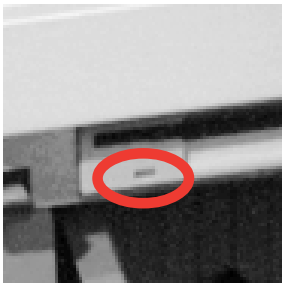
1. Touch the Util folder tab.
2. Touch the Maintenance button.
3. Touch the Finalization Maintenance button to access the 'Finalization Maintenance' pop-up window.
4. Touch Start.

2.19 Analyzer Power OFF Recommendations

Analyzer Power OFF Recommendations

Power OFF the analyzer using the operation switch. Leave the circuit breaker ON. Power to the circuit breaker keeps the reagent disk temperature-controlled.

Make sure that the disk drive is not active (i.e., the analyzer is in Stand-by) when you power off the analyzer. The system is updating files on the data disk when the light is active.



In addition, close the lids on the ProCell/ CleanCell bottles to prevent evaporation.

Close ProCell/CleanCell bottles

If the analyzer is to be powered OFF at the circuit breaker, move reagent packs to the refrigerator as temperature control to the reagent disk will be off. Make sure that the reagent pack lids are tightly closed.

If the analyzer is to be powered OFF for longer than 7 days, please refer to Chapter 4, Maintenance – *User's Guide*, for further details.

Chapter 3
How To...

3.1 How To Load Controls for Control of Calibration – Disk System

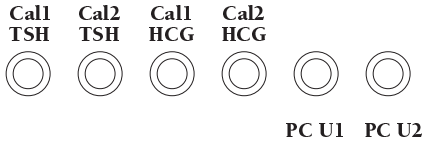
Introduction

Any control placed on the sample disk DIRECTLY after an assay CalSet is measured with the successful calibration curve of the just-calibrated reagent pack. Even if this control is defined to be run on multiple assays, it only measures the assay calibrated. If the calibration is questionable or failed, the control results are based on the last valid calibration.

To run controls on all assays being calibrated, you must leave a gap between the last CalSet and the first control. The Results report prints that the control was used for calibration. Refer to the examples shown below for various options and examples of a section of a Results report.

Example A

Control of calibration occurs for HCGSTAT because the controls were placed directly after HCGSTAT Cal 2. Controls are NOT run for TSH.



Control Loading

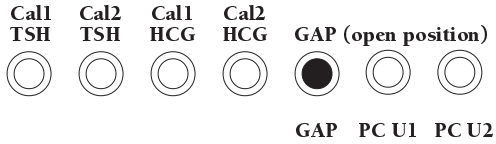
```
Results                    Operator ID: 10            04/08/1998  10:30
-------

Control ID     : PC U1                    Seq No.        : 29
Disk - Pos.    : 0- 5                     Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
HCGSTAT        6.34 mIU/ml          [    5.73-   10.63]          11:47

This control is used for Calibration QC : Test Code   Lot No.  Rgt Pack No.
                                          ---------------------------------
                                          HCGSTAT      194538        2264

Control ID     : PC U2                    Seq No.        : 30
Disk - Pos.    : 0- 6                     Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
HCGSTAT       37.85 mIU/ml          [   29.86-   45.74]          11:48

This control is used for Calibration QC : Test Code   Lot No.  Rgt Pack No.
                                          ---------------------------------
                                          HCGSTAT      194538        2264
```

Example Results report with control of calibration

3.1 How To Load Controls for Control of Calibration – Disk System

Example B

Controls are performed on both TSH and HCGSTAT (provided those assays are defined for PC U1/U2 in CONTROL DEFINITION).



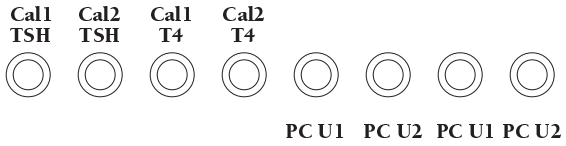
Control Loading

```
Results                    Operator ID: 10            04/08/1998  10:30
-------

Control ID     : PC U1                     Seq No.        : 29
Disk - Pos.    : 0- 6                      Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
TSH            1.85 uIU/ml        [    1.37-    1.97]          11:47
HCGSTAT        6.34 mIU/ml        [    5.73-   10.63]          11:48

Control ID     : PC U2                     Seq No.        : 30
Disk - Pos.    : 0- 7                      Sampling Date  : 04/08/1998 10:22

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
TSH           12.04 uIU/ml        [    9.69-   13.11]          11:49
HCGSTAT       37.85 mIU/ml        [   29.86-   45.74]          11:50
```

Example Results report with controls on both assays calibrated

Example C

Control of calibration occurs for T4 because the controls were placed directly after T4 Cal2. Controls (second set) are performed on both TSH and T4 (provided those assays are defined for PC U1/U2 in CONTROL DEFINITION) utilizing the calibration curves for the reagent packs currently in use to run samples. This situation could occur when a new lot of reagent needs to be calibrated and controlled, but the old reagent lot is still on the analyzer and must also be controlled.

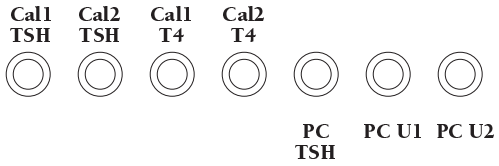


Control Loading

3.1 How To Load Controls for Control of Calibration – Disk System

Example D

TSH is performed on PC TSH, while TSH and T4 are performed on PC U1/U2 (provided those assays are defined for PC U1/U2 in CONTROL DEFINITION). In this case, PC TSH serves as the "gap" between the last CalSet and the first control set.



Control Loading

3.2 How To Load Controls for Control of Calibration – Rack System

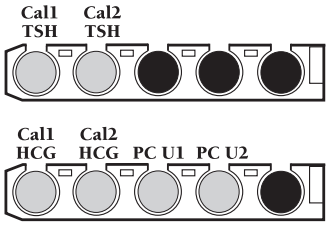
Introduction

Any control placed on the sample rack DIRECTLY after an assay CalSet is measured with the successful calibration curve of the just-calibrated reagent pack. Even if this control is defined to be run on multiple assays, it only measures the assay calibrated. If the calibration is questionable or failed, the control results are based on the last valid calibration.

To run controls on all assays being calibrated, you must leave a gap between the last CalSet and the first control. ***Remember – you cannot split a CalSet between racks.*** The Results report prints that the control was used for calibration. Refer to the examples shown below for various options and examples of a section of a Results report. On the examples below, a black circle signifies an open rack position.

Example A

Control of calibration occurs for HCGSTAT because the controls were placed directly after HCGSTAT Cal 2. Controls are NOT run for TSH.



Control Loading

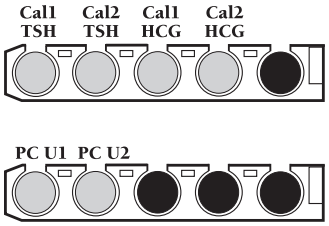
```
Results                    Operator ID: 10             04/08/1998  10:30
-------

Control ID     : PC U1                      Seq No.        : 29
Rack ID - Pos. : 0010 - 3                   Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
HCGSTAT        6.34 mIU/ml          [    5.73-   10.63]          11:47

This control is used for Calibration QC : Test Code   Lot No.  Rgt Pack No.
                                          ---------------------------------
                                          HCGSTAT      194538        2264

Control ID     : PC U2                      Seq No.        : 30
Rack ID - Pos. : 0010 - 4                   Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
HCGSTAT       37.85 mIU/ml          [   29.86-   45.74]          11:48

This control is used for Calibration QC : Test Code   Lot No.  Rgt Pack No.
                                          ---------------------------------
                                          HCGSTAT      194538        2264
```

Example Results report with control of calibration

3.2 How To Load Controls for Control of Calibration – Rack System

Example B

Controls are performed on both TSH and HCGSTAT (provided those assays are defined for PC U1/U2 in CONTROL DEFINITION).



Control Loading

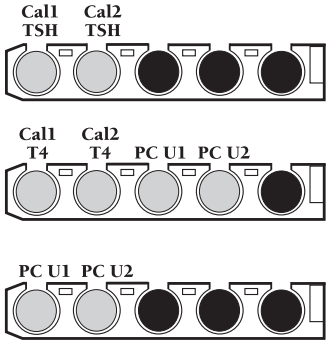
```
Results                    Operator ID: 10             04/08/1998  10:30
-------

Control ID     : PC U1                    Seq No.        : 29
Rack ID - Pos. : 0010 - 3                 Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
TSH            1.85 uIU/ml        [    1.37-    1.97]           11:47
HCGSTAT        6.34 mIU/ml        [    5.73-   10.63]           11:48

Control ID     : PC U2                    Seq No.        : 30
Rack ID - Pos. : 0010 - 4                 Sampling Date  : 04/08/1998 10:20

Test Code    Result    Unit    Dil.   Exp. Values       Note    Ready Flag
-------------------------------------------------------------------------
TSH           12.04 uIU/ml        [    9.69-   13.11]           11:49
HCGSTAT       37.85 mIU/ml        [   29.86-   45.74]           11:50
```

Example Results report with controls on both assays calibrated

3.2 How To Load Controls for Control of Calibration – Rack System

Example C

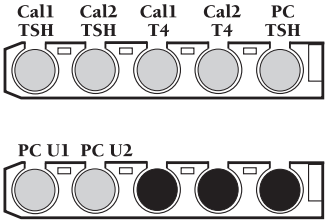
Control of calibration occurs for T4 because the controls were placed directly after T4 Cal2. Controls (second set) are performed on both TSH and T4 (provided those assays are defined for PC U1/U2 in CONTROL DEFINITION) utilizing the calibration curves for the reagent packs currently in use to run samples. This situation could occur when a new lot of reagent needs to be calibrated and controlled, but the old reagent lot is still on the analyzer and must also be controlled.



Control Loading

Example D

TSH is performed on PC TSH, while TSH and T4 are performed on PC U1/U2 (provided those assays are defined for PC U1/U2 in CONTROL DEFINITION). In this case, PC TSH serves as the “gap” between the last CalSet and the first control set.



Control Loading

3.3 How To Manually Select Calibration for a Reagent Pack

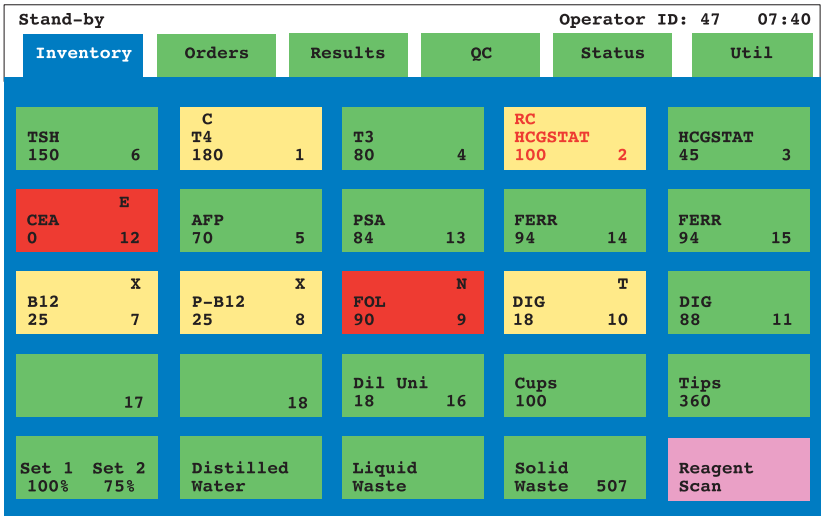
Introduction

Manual calibration selection of reagent packs makes calibration of multiple reagent packs easier. The following examples describe two of the most likely uses of manual calibration selection.

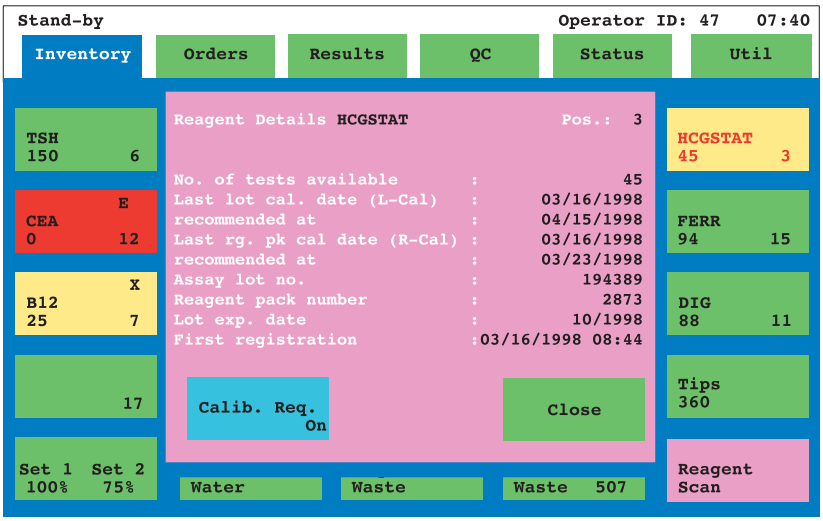
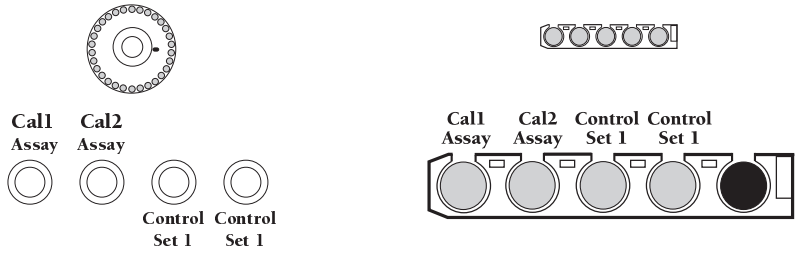
Procedure - Bottle Changeover Calibration

Follow the instructions below to manually select calibration for a bottle changeover calibration. The following criterion apply:

- single assay
- reagent pack A: existing lot with valid L-Cal, but you would like to calibrate this pack today
- reagent pack B: brand new lot; calibration is required ("RC" is displayed on the INVENTORY test button).

STEP	ACTION
1	Load the new reagent pack on the reagent disk. Touch Inventory to access the INVENTORY screen.
2	Touch Reagent Scan to initiate a reagent scan. During the scan the analyzer prioritizes automatic calibration for the new lot of reagent (reagent pack B). The new pack appears with an "RC" on the button. 
3	Touch the test button of the assay that you want to calibrate today. This accesses the 'Reagent Details' pop-up window for that assay.

3.3 How To Manually Select Calibration for a Reagent Pack

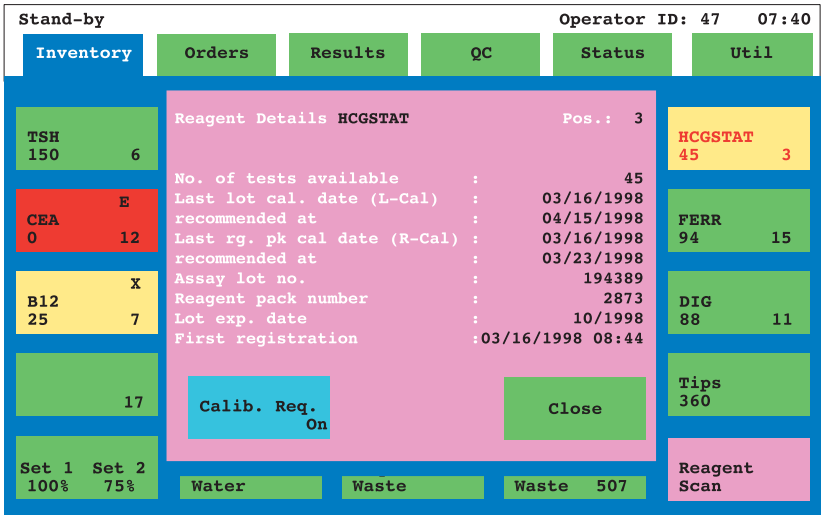
STEP	ACTION
4	Touch the Calib. Req. On button and toggle the choice to "On." The button turns light blue when selected. 
5	Touch Close to exit the pop-up window.
6	Load the appropriate CalSet on the sample carrier followed by the appropriate controls. 
7	Press Start to initiate calibration.

The analyzer calibrates both reagent packs. Both reagent packs are controlled. The Results report identifies by reagent pack number which reagent was controlled. Samples and additional controls are pipetted from reagent pack A until depleted. Then samples and controls are pipetted from reagent pack B.

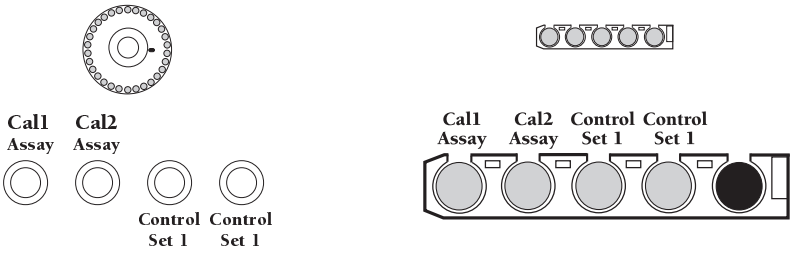
3.3 How To Manually Select Calibration for a Reagent Pack

Procedure - Single Assay/Single Lot; Multiple Reagent Packs

Follow the instructions below to manually select calibration when operating with multiple reagent packs of single lot of a single assay.

STEP	ACTION
1	The analyzer prioritizes automatic calibration for the reagent pack in the lowest reagent disk position. To calibrate additional reagent packs, touch the button for the reagent pack to be calibrated. This accesses the 'Reagent Details' pop-up window for that assay.
2	Touch the Calib. Req. On button and toggle the choice to "On." The button turns light blue when selected. 
3	Touch Close to exit the pop-up window.
4	Repeat steps 1 - 3 for each reagent pack that requires calibration.

3.3 How To Manually Select Calibration for a Reagent Pack

STEP	ACTION
5	Load the appropriate CalSet on the sample carrier followed by the appropriate controls. 
6	Press Start to initiate calibration.

The analyzer calibrates each reagent pack and each reagent pack is controlled. The reagent pack used for the control is identified on the Results report.

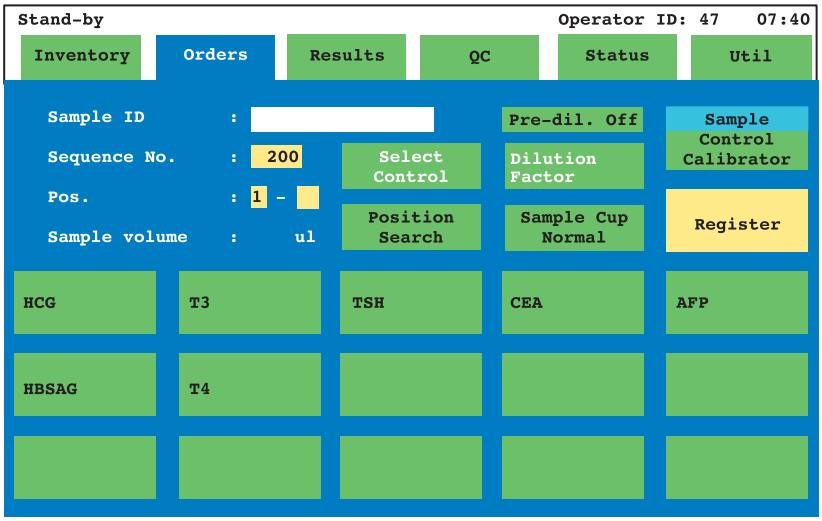
3.4 How to Manually Select a Calibrator – Disk System

Introduction

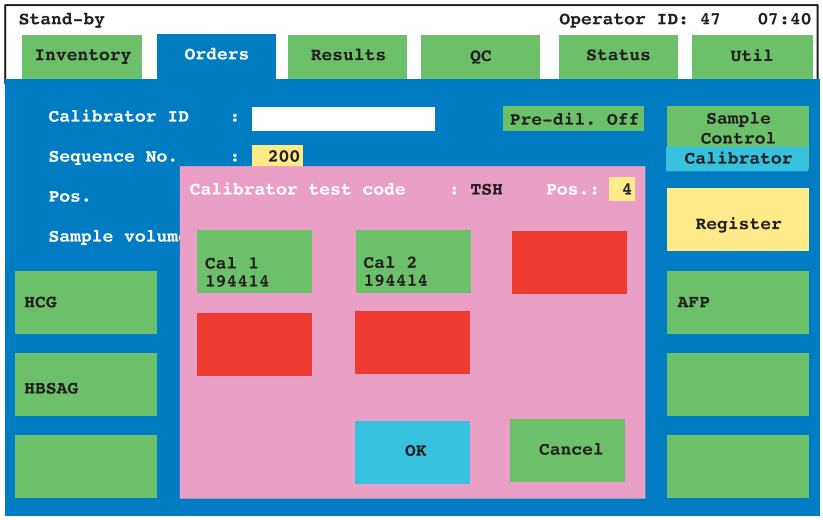
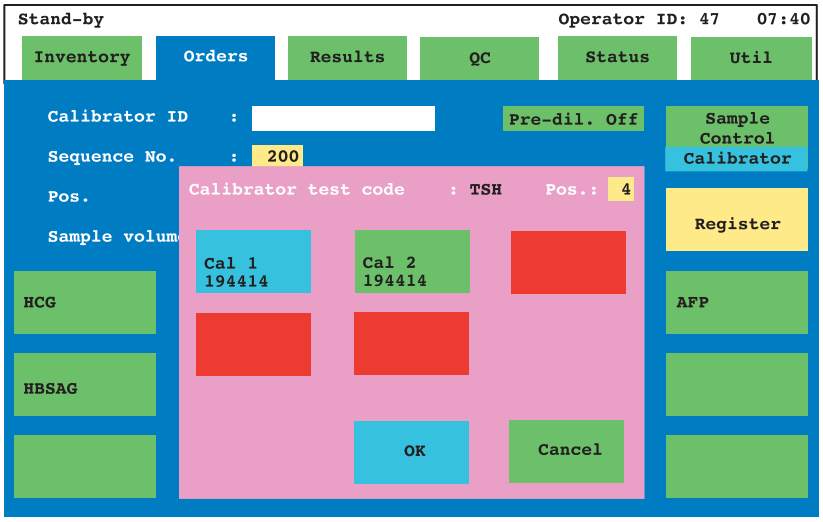
You can manually select a calibrator from the 'Select Calibrator' pop-up window within the ORDERS screen. This button is useful if you pour your calibrators into a container other than the CalSet vial.

Procedure

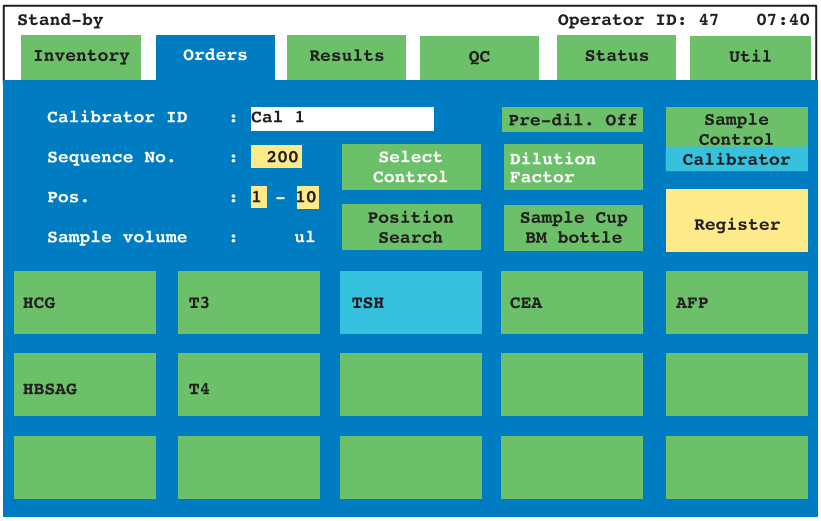
Follow the instructions below to manually select a calibrator.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	Touch the Sample Control Calibrator button to toggle to the "Calibrator" choice. The `Sample ID` field changes to `Calibrator ID`.

3.4 How to Manually Select a Calibrator – Disk System

STEP	ACTION
3	Touch the test button for the assay to be calibrated. This accesses the 'Select Calibrator' pop-up window. 
4	Touch the appropriate calibrator test button. The button turns light blue when selected. 
5	Touch OK to exit the window.

3.4 How to Manually Select a Calibrator – Disk System

STEP	ACTION
6	Touch the second Pos. field. Type the desired sample disk position. Press Enter. Place the calibrator at the designated position on the disk.
7	If running in the multiple disk mode, touch the first disk Pos. field. Type a disk number (0-9) and press Enter. 
8	Touch Register to register the calibrator. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • The next available sample position is displayed.
9	Repeat steps 2 - 7 for any additional calibrators.

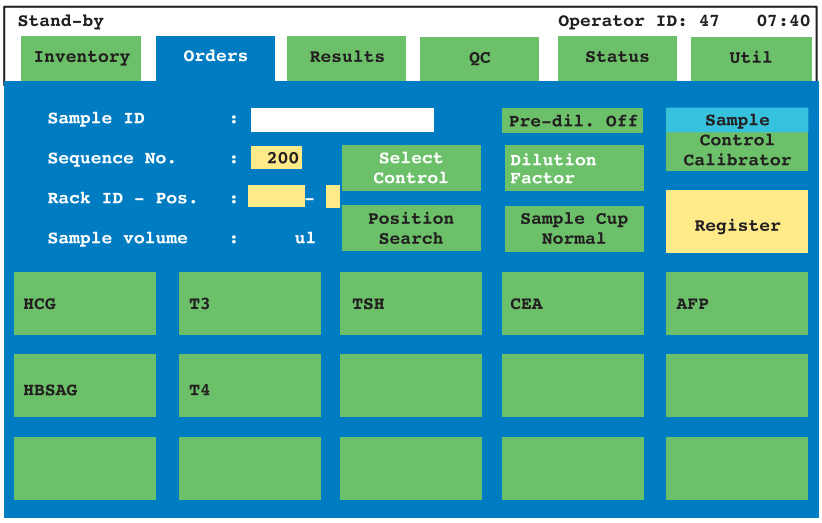
3.5 How to Manually Select a Calibrator – Rack System

Introduction

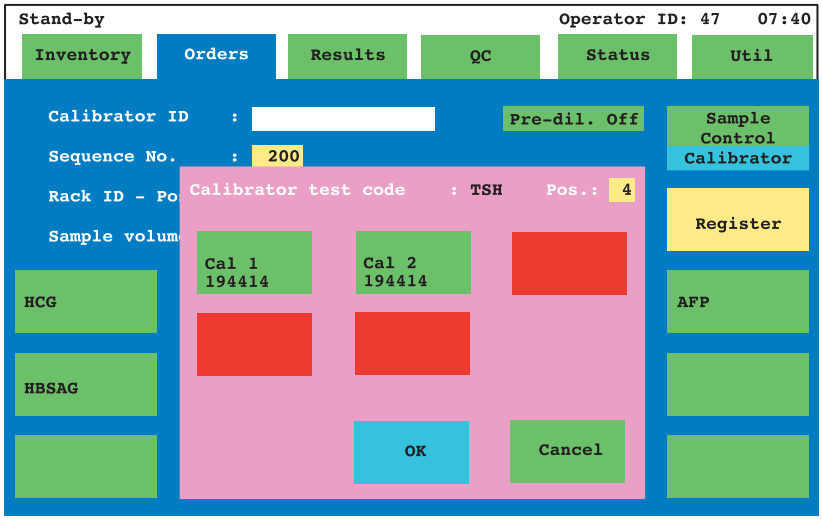
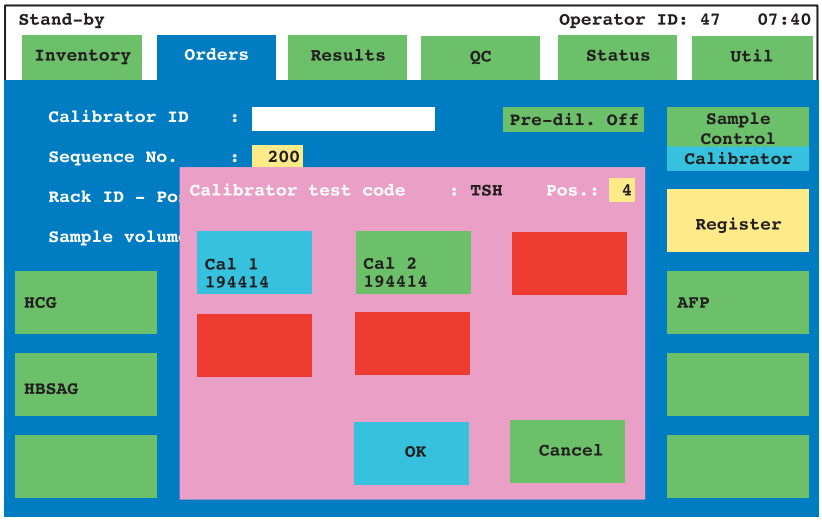
You can manually select a calibrator from the 'Select Calibrator' pop-up window within the ORDERS screen. This button is useful if you pour your calibrators into a container other than the CalSet vial.

Procedure

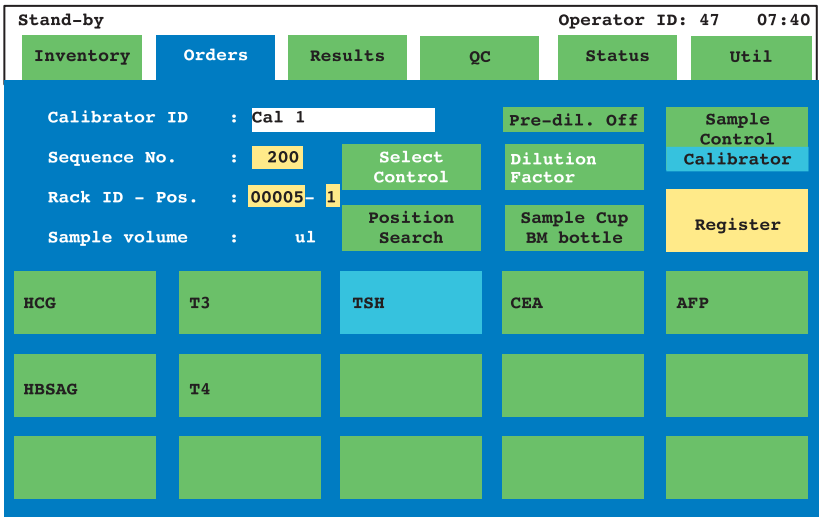
Follow the instructions below to manually select a calibrator.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	Touch the Sample Control Calibrator button to toggle to the "Calibrator" choice. The `Sample ID` field changes to `Calibrator ID`.

3.5 How to Manually Select a Calibrator – Rack System

STEP	ACTION
3	Touch the test button for the assay to be calibrated. This accesses the 'Select Calibrator' pop-up window. 
4	Touch the appropriate calibrator test button. The button turns light blue when selected. 
5	Touch OK to exit the window.

3.5 How to Manually Select a Calibrator – Rack System

STEP	ACTION
6	Touch the Rack ID field. Type the appropriate rack ID. Press Enter.
7	The cursor moves to the Rack Pos. field. Type a rack position number (0-5) and press Enter. Place the calibrator at the designated position on the rack. 
8	Touch Register to register the calibrator. • The cursor returns to the Sample ID field. • The Sequence No. increments by one. • For rack positions 1 - 4, the Rack Pos. increments by one. For position 5, the Rack Pos. returns to 1. • For rack positions 1 - 4, the Rack ID remains unchanged. For position 5, the Rack ID clears.
9	Repeat steps 2 - 8 for any additional calibrators.

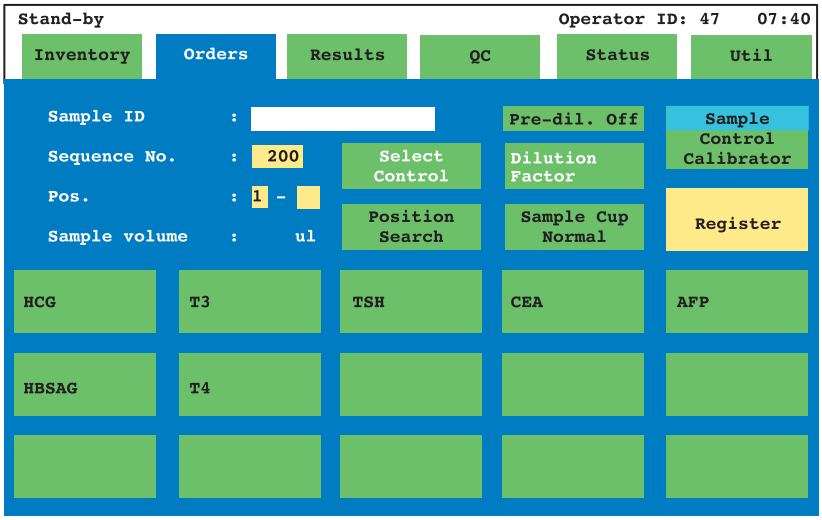
3.6 How To Delete a Single Open Request

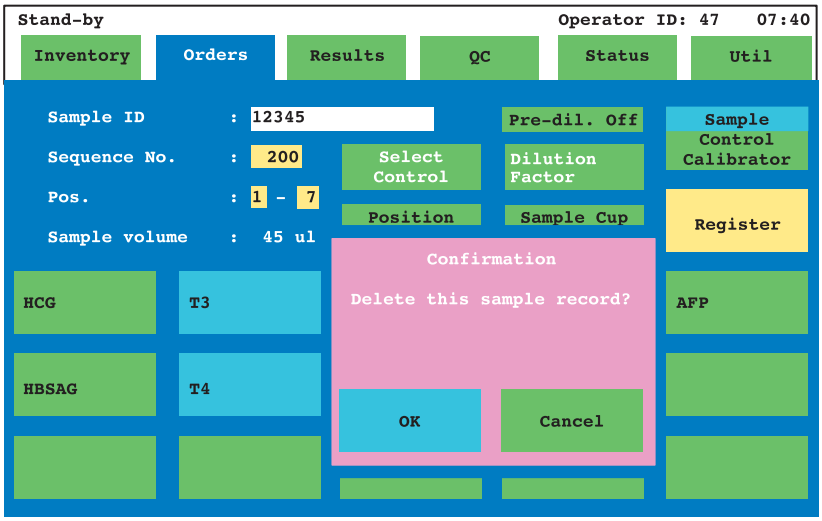
Introduction

You can delete single open requests from the 'Confirmation' pop-up window within the ORDERS screen. While the screens in the procedure below are for a disk system, the steps involved apply to the disk system and the rack system.

Procedure

Follow the instructions below to delete a single open request.

STEP	ACTION
1	Touch Orders to access the ORDERS screen. 
2	If the sample to be deleted has a numeric ID, touch the Sample ID field. If the ID is alphanumeric, proceed to step 4.
3	Type the sample ID number to be deleted. Press Enter. Proceed to step 5.
4	If the sample to be deleted has an alphanumeric ID, touch the Sequence No. field. Press Next ▼ or ▲ Prev until you find the sample to be deleted.

STEP	ACTION
5	While the cursor is in either the Sample ID or Sequence No. field, press C to access the Delete Sample 'Confirmation' pop-up window. 
6	Touch OK to delete the sample.

3.7 How To Manually Upload Results

Introduction

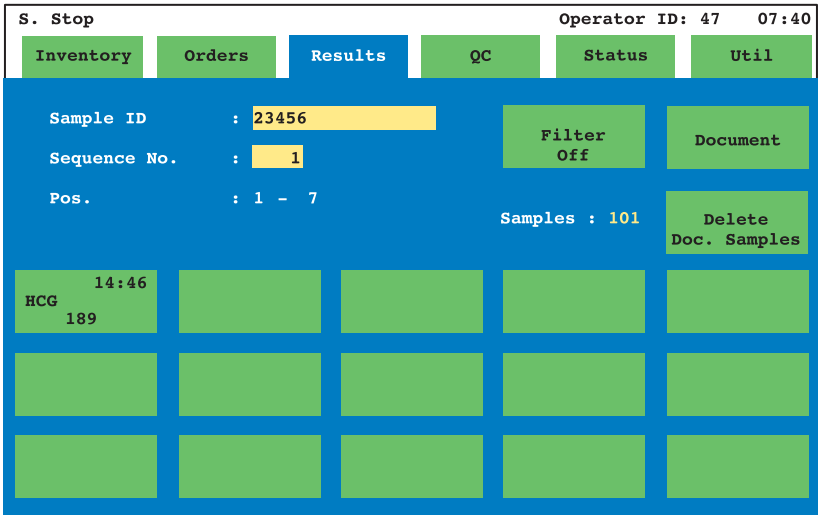
If you have automatic uploading OFF and you are interfaced with a host computer, you must upload sample results manually. Results may be uploaded more than once, if necessary.

While the screens in the procedure below are for a disk system, the steps involved apply to the disk system and the rack system.

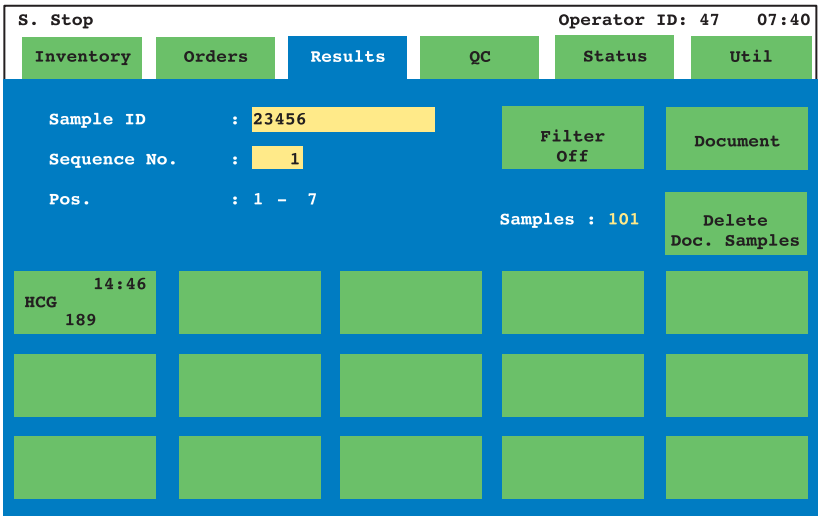
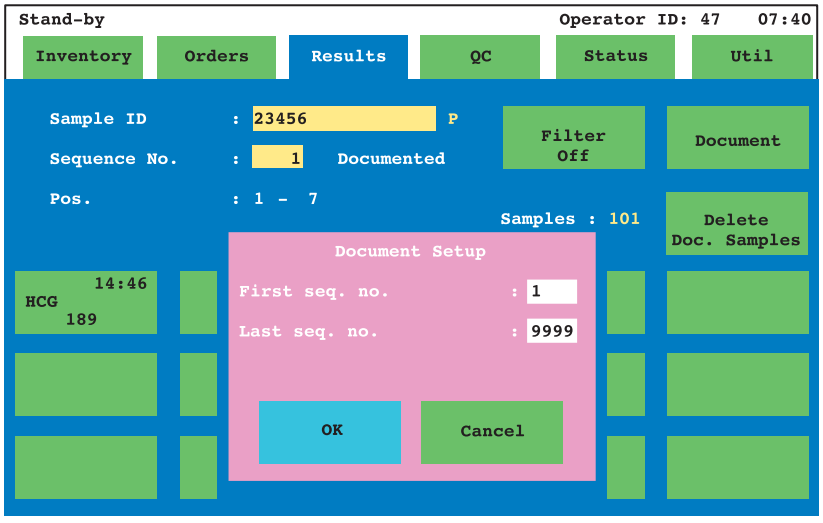
Procedure

Follow the instructions below to manually upload results.

To upload a SINGLE result:

STEP	ACTION
1	Touch Results to access the RESULTS screen. 
2	If sample ID to be uploaded is numeric, touch the Sample ID field. If the ID is alphanumeric, proceed to step 4.
3	Type the sample ID number to be uploaded. Press Enter. Proceed to step 5.
4	If the sample ID to be uploaded is alphanumeric, touch the Sequence No. field. Press Next ▼ or ▲ Prev until you reach the desired sample ID.
5	Press Doc to upload the sample result(s) to the host.

To upload MULTIPLE results:

STEP	ACTION
1	Touch Results to access the RESULTS screen. 
2	Touch Filter Off to verify your filter settings. What uploads depends upon whether Filtering is ON and what selections are made in the 'Filter Selection' pop-up window.
3	Touch Document to access the 'Document Setup' pop-up window. 

3.7 How To Manually Upload Results

STEP	ACTION
4	Touch the `First seq. no.` field. Select the first sequence number in the range of samples to upload.
5	Touch the `Last seq. no.` field. Select the last sequence number in the range of samples to upload.
6	Touch OK to activate the upload. The range of sequence numbers selected are uploaded to the host.

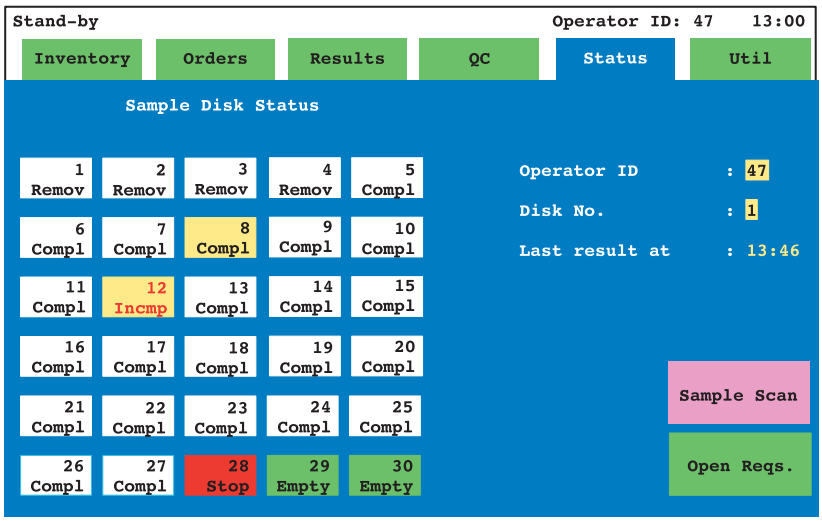
3.8 How To Delete Open Requests – Disk System

Introduction

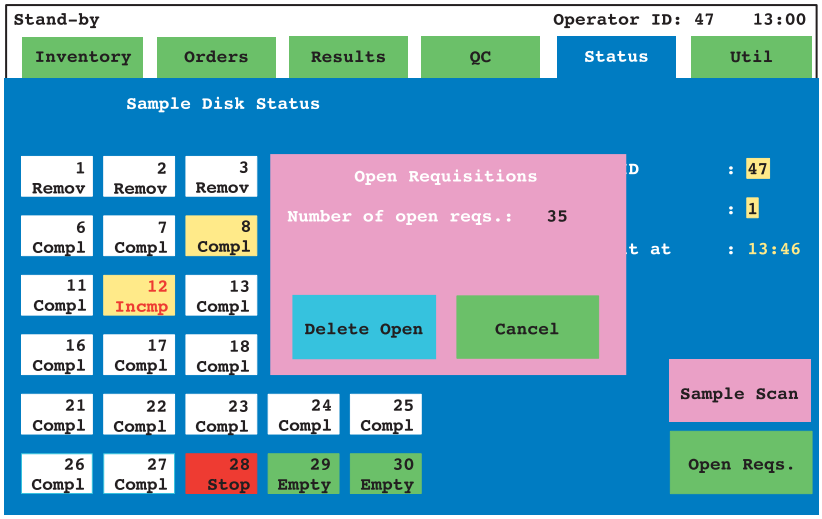
You can delete multiple samples with open requests from the 'Confirmation' pop-up window within the STATUS screen. The samples deleted are those for the sample disk number currently displayed on the screen.

Procedure

Follow the instructions to delete open requests.

STEP	ACTION
1	Touch Status to access the STATUS screen. 
2	Touch the `Disk No.` field.
3	Type the sample disk number for which requisitions are to be deleted. Press Enter.

3.8 How To Delete Open Requests – Disk System

STEP	ACTION
4	Touch Open Reqs. to access the 'Open Requisitions' pop-up window. 
5	Touch Delete Open to delete open test requests. *The STATUS screen only displays samples that have been assigned a position. To ensure a complete clear of all open requests, repeat this procedure for all disk numbers.*

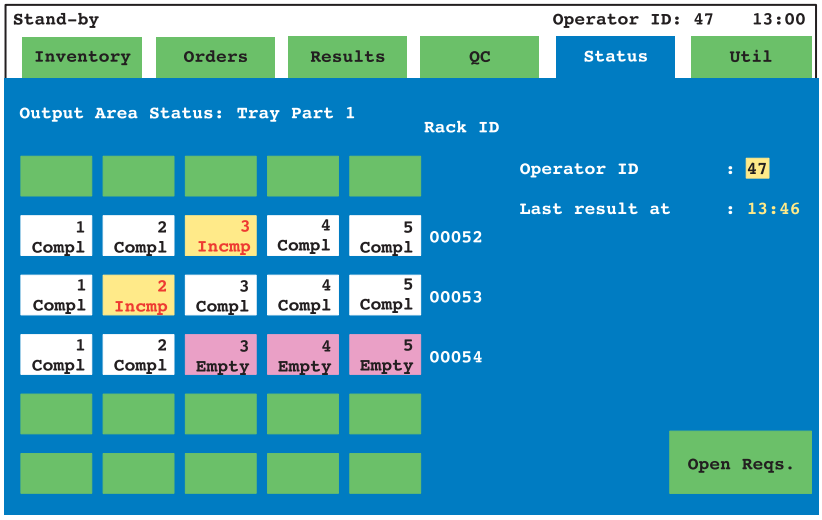
3.9 How To Delete Open Requests – Rack System

Introduction

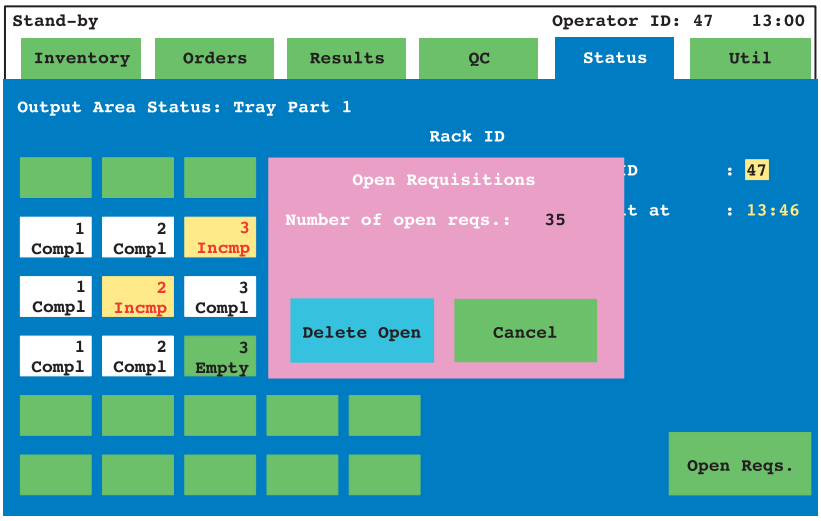
You can delete multiple samples with open requests from the ‘Confirmation’ pop-up window within the STATUS screen.

Procedure

Follow the instructions to delete open requests.

STEP	ACTION
1	Touch Status to access the STATUS screen. 

3.9 How To Delete Open Requests – Rack System

STEP	ACTION
2	Touch Open Reqs. to access the 'Open Requisitions' pop-up window. 
3	Touch Delete Open to delete open test requests.

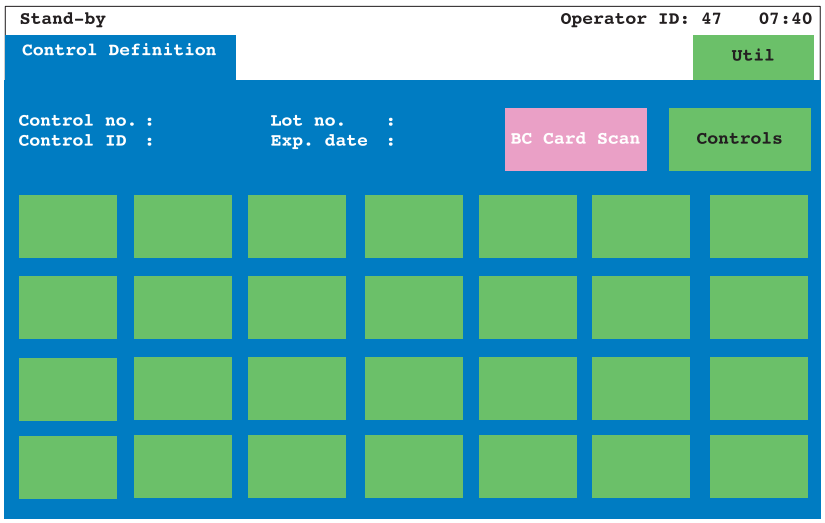
3.10 How To Define Roche (Bar-Coded) Controls

Introduction

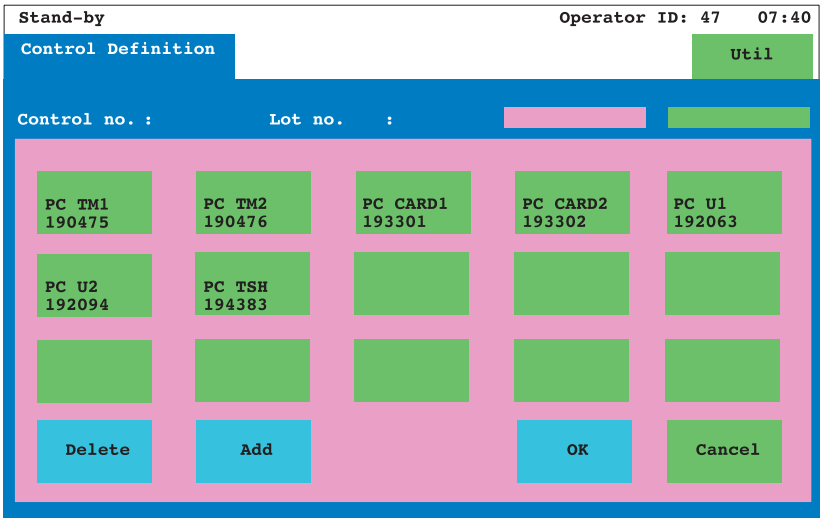
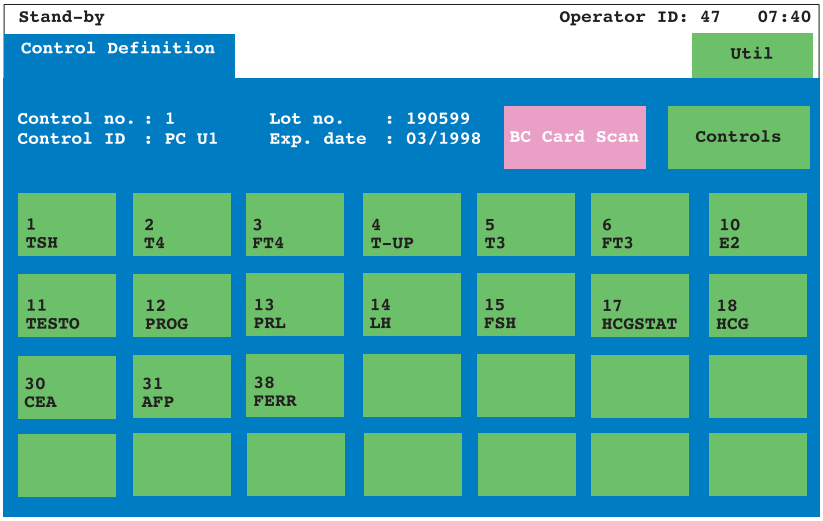
Before you can run controls or make manual control selections, you must define your controls in the CONTROL DEFINITION screen.

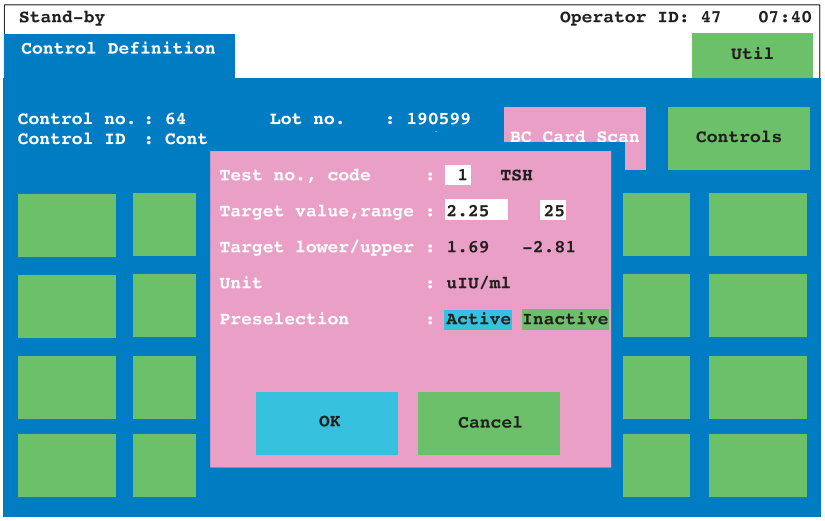
Procedure

Follow the instructions below to define Roche (bar-coded) controls.

STEP	ACTION
1	Touch Util to access the UTIL screen.
2	Touch Control Definition to access the CONTROL DEFINITION screen. 
3	Insert the control bar code card into the card reading station. The bar code must face toward the back of the analyzer. Push the card as far down as it will go into the station.
4	Touch BC Card Scan to initiate the bar code card scan. The scan was successfully scanned when you hear the bar code reader beep. Allow the analyzer to return to Stand-by. Repeat for each control card.

3.10 How To Define Roche (Bar-Coded) Controls

STEP	ACTION
5	Touch Controls to access the 'Control Definition' pop-up window. 
6	Touch the desired control button for which you need to make test selections. The button turns light blue when selected.
7	Touch OK to close the window and return to the CONTROL DEFINITION screen. Now, the available assays for this control appear on the buttons. 

STEP	ACTION
8	Touch a desired test button for the control. Touching a test button accesses the 'Control Definition Details' pop-up window. This window shows the test number, test code, target value, target range, lower and upper control limit values and unit of measure.
9	Touch "Active" in the Preselection field. This activates the assay for the controls and allows you to deselect it from the ORDERS screen at a later time, if necessary. If you do not activate the assay, the analyzer does not perform that assay on the control when the control vial is scanned during operation. 
10	Touch OK to close the pop-up window and return to CONTROL DEFINITION.
11	Repeat steps 8-10 for each additional assay to be performed on the control.

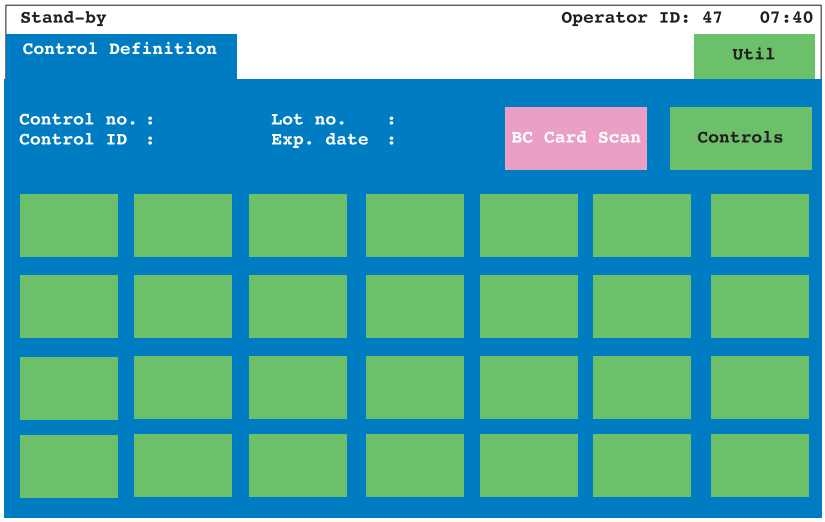
3.11 How To Define Non-Roche (Non-Bar-Coded) Controls

Introduction

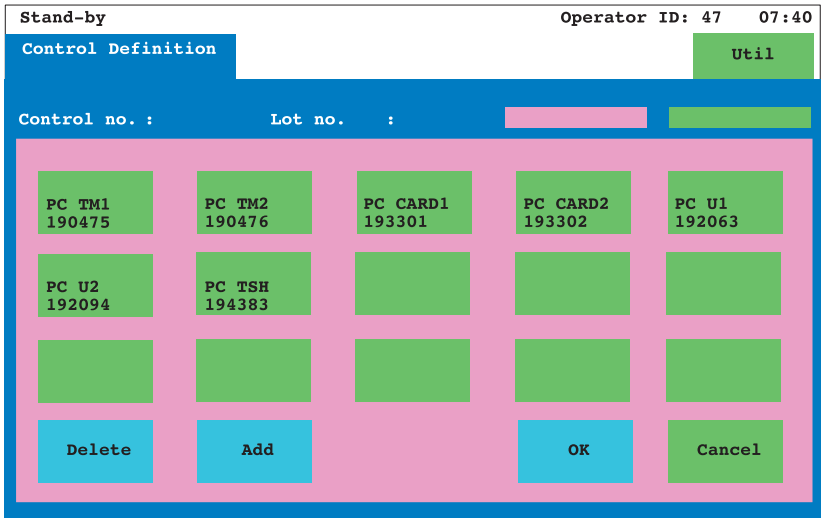
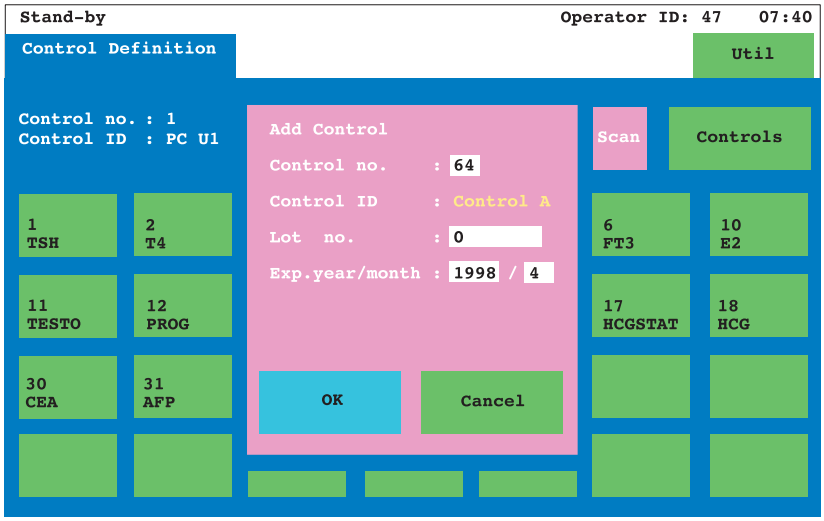
Before you can run controls or make manual control selections, you must define your controls in the CONTROL DEFINITION screen.

Procedure

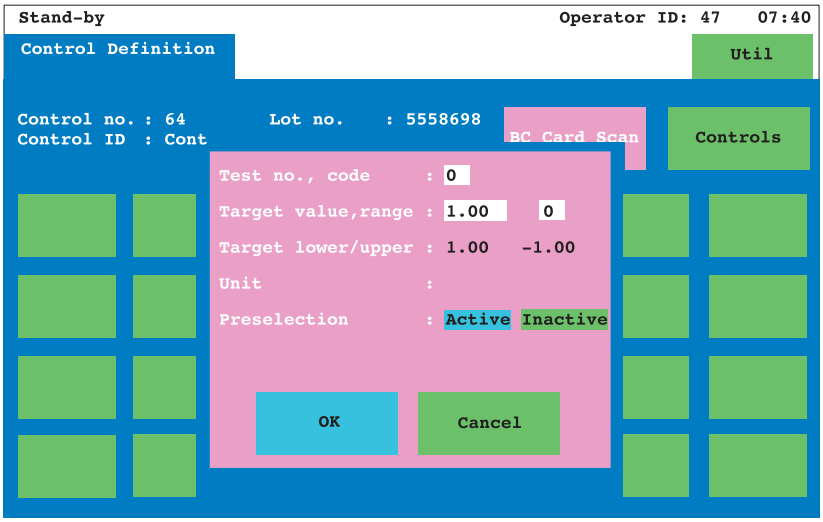
Follow the instructions below to define non-Roche (non-bar-coded) controls.

STEP	ACTION
1	Touch Util to access the UTIL screen.
2	Touch Control Definition to access the CONTROL DEFINITION screen. 

3.11 How To Define Non-Roche (Non-Bar-Coded) Controls

STEP	ACTION
3	Touch Controls to access the 'Control Definition' pop-up window. 
4	Touch one of the blank buttons on the window and then touch Add. This accesses the 'Add Control' pop-up window. The Control number defaults to "64" and the Control ID defaults to "Control A." To use Control B, change the Control number to "65." To use Control C, change the Control number to "66," etc. 

3.11 How To Define Non-Roche (Non-Bar-Coded) Controls

STEP	ACTION
5	Touch the `Lot no.` field. Type the lot number (max. 8 characters) of the non-Roche control and press Enter.
6	Touch the first `Exp.year/month` field. Type the four-digit year of the expiration date of the non-Roche control and press Enter.
7	Touch the second `Exp.year/month` field. Type the month of the expiration date of the non-Roche control and press Enter.
8	Touch OK. The window closes and returns to the 'Control Definition' pop-up window.
9	Touch OK. The window closes and returns to CONTROL DEFINITION.
10	Touch a blank test button to define the first assay to be performed on the non-Roche control. This accesses the 'Control Definitions Detail' pop-up window. 

3.11 How To Define Non-Roche (Non-Bar-Coded) Controls

STEP	ACTION
11	Touch the `Test no., code` field. Type the test number for the desired test and press Enter. After pressing Enter, the test code appears next to the number. (A list of test numbers can be obtained from the TEST CONDITIONS screen.) *You can only select test numbers/codes for assays currently on the reagent disk.*
12	Touch the first `Target value,range` field. Type the target value (max. 7 characters) for the assay and press Enter.
13	Touch the second `Target value,range` field. Type the range for the assay and press Enter. The range is a percentage of the target value that is then added or subtracted from the previously entered target value.
14	Touch "Active" in the `Preselection` field. The color changes to light blue. This activates the assay for the control and allows you to deselect it from the ORDERS screen at a later time, if necessary. If you do not activate the assay, the analyzer does not perform that assay on the control when the control is selected.
15	Touch OK. The window closes and returns to CONTROL DEFINITION.
16	Repeat steps 10-15 for assays to be defined on the non-Roche control.

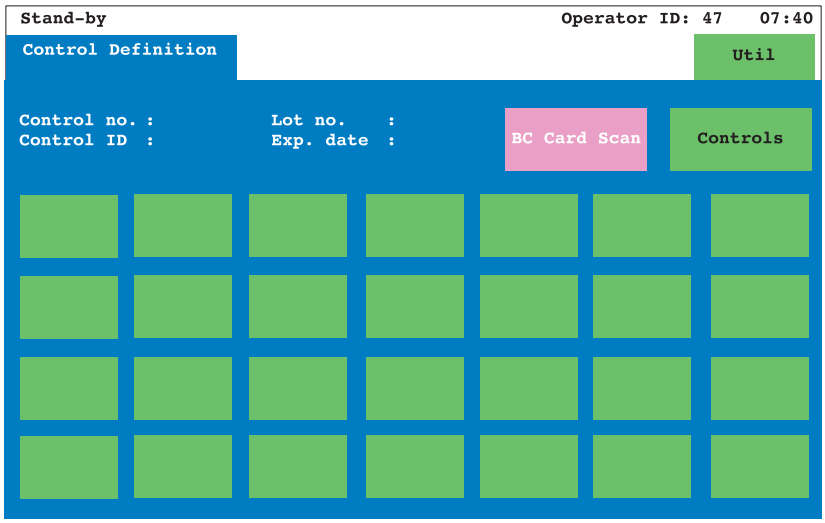
3.12 How To Change a Control Target or Range

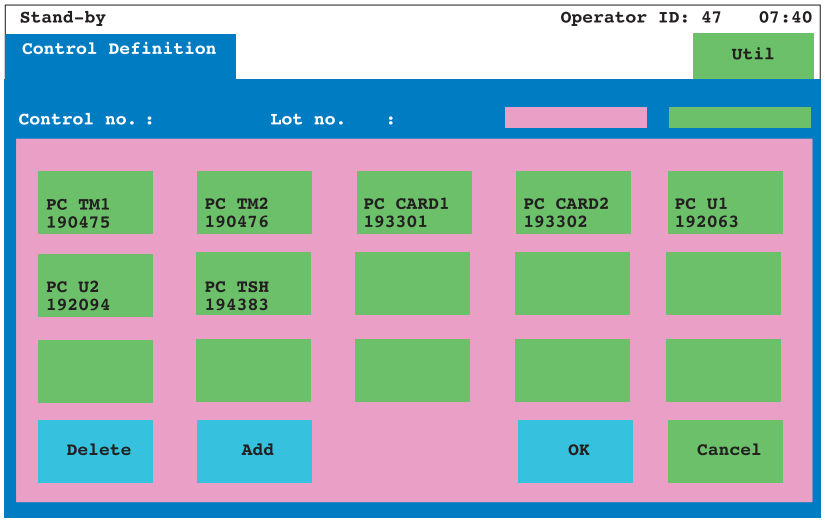
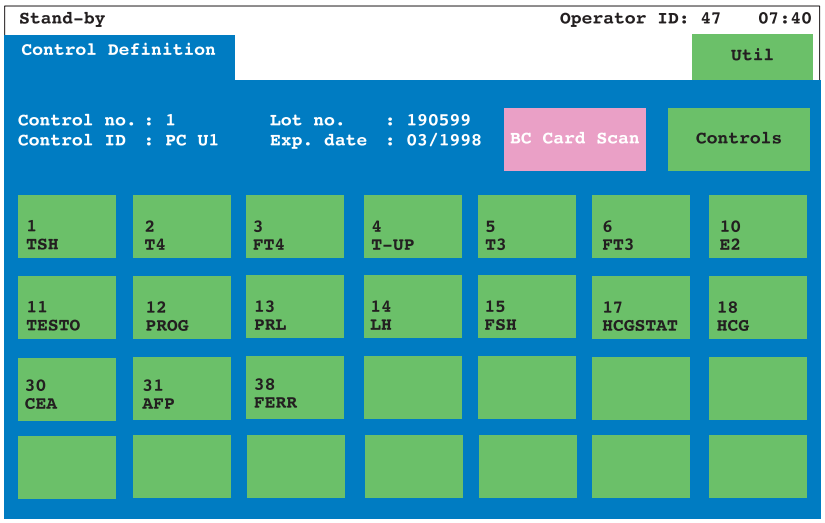
Introduction

Each laboratory should establish its own control ranges. In addition, there may be times that you need to change the established control ranges of either a Roche or non-Roche control.

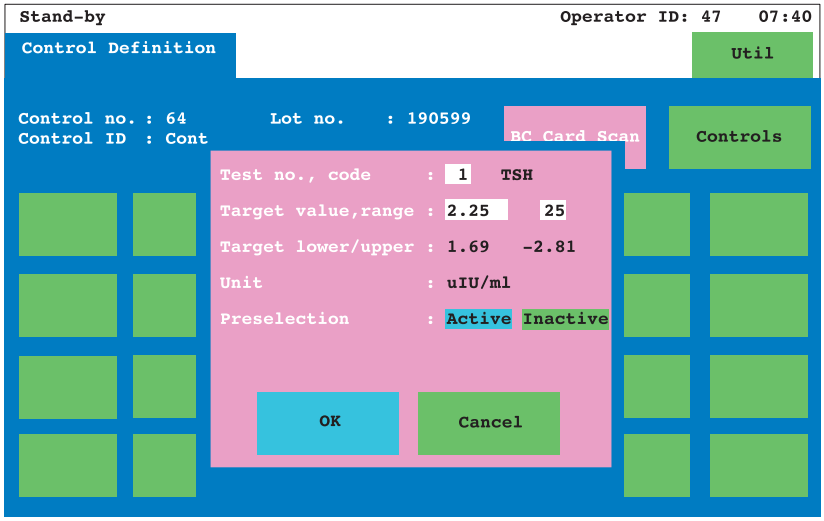
Procedure

Follow the instructions below to change a control target or range.

STEP	ACTION
1	Touch Util to access the UTIL screen.
2	Touch Control Definition to access the CONTROL DEFINITION screen. 

STEP	ACTION
3	Touch Controls to access the 'Control Definition' pop-up window. 
4	Touch the desired control button for which you need to change control values. The button turns light blue when selected.
5	Touch OK to close the window and return to the CONTROL DEFINITION screen. Now, the available assays for this control appear on the buttons. 

3.12 How To Change a Control Target or Range

STEP	ACTION
6	Touch test button that requires the changed control values. Touching a test button accesses the 'Control Definition Details' pop-up window. 
7	Touch the first `Target value,range` field. Type the revised target value (max. 7 characters) for the assay and press Enter.
8	Touch the second `Target value,range` field. Type the revised range for the assay and press Enter. The range is a percentage of the target value that is then added or subtracted from the previously entered target value. After pressing Enter the revised range appears in the `Target lower/upper` field.
9	Verify that "Active" is light blue in the `Preselection` field.
10	Touch OK to close the pop-up window and return to CONTROL DEFINITION.
11	Repeat steps 6-10 for each additional assay that requires changes to its control values.

3.13 How To Change Expected Values

Introduction

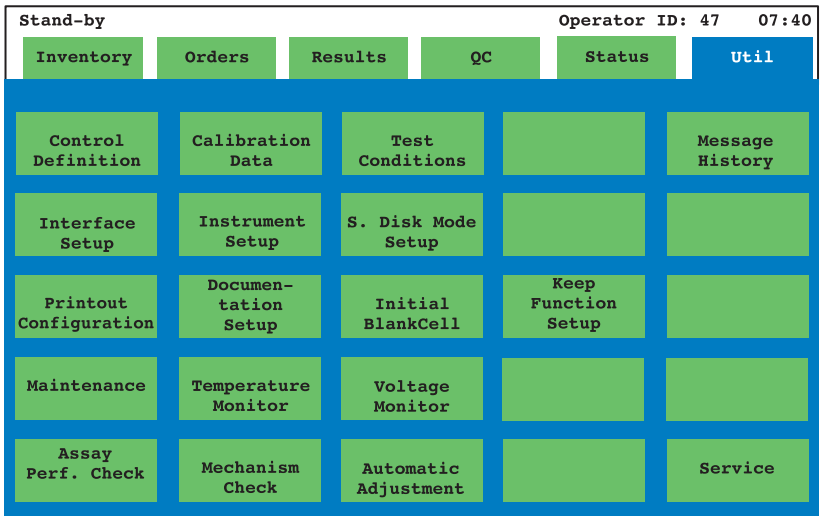
Each laboratory should establish its own expected values. In addition, many assays have multiple units of measure. The primary unit (i.e., that unit which is initially displayed when the software is loaded) encoded in the reagent bar code may not be the unit you wish to use in your laboratory. Use the 'Test Conditions Details' pop-up window to change these assay details. If you change both the expected values and the unit of measure, change the unit first.

While the screens in the procedure below are for a disk system, the steps involved apply to the disk system and the rack system.

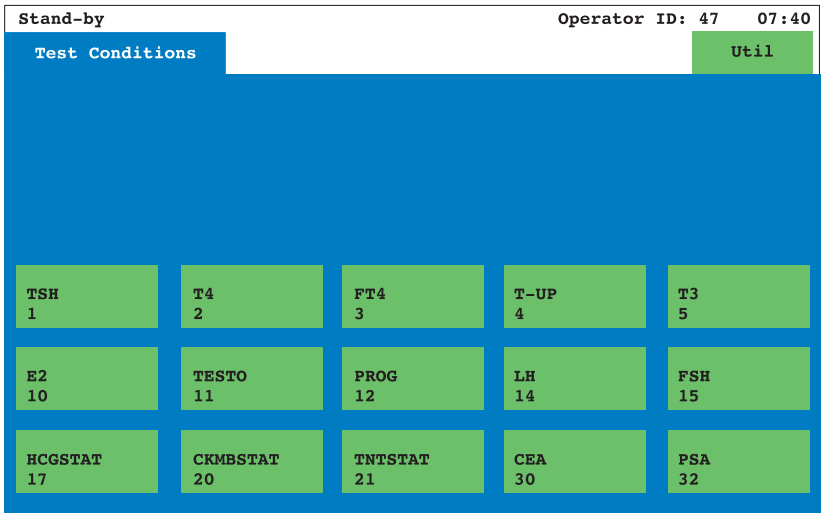
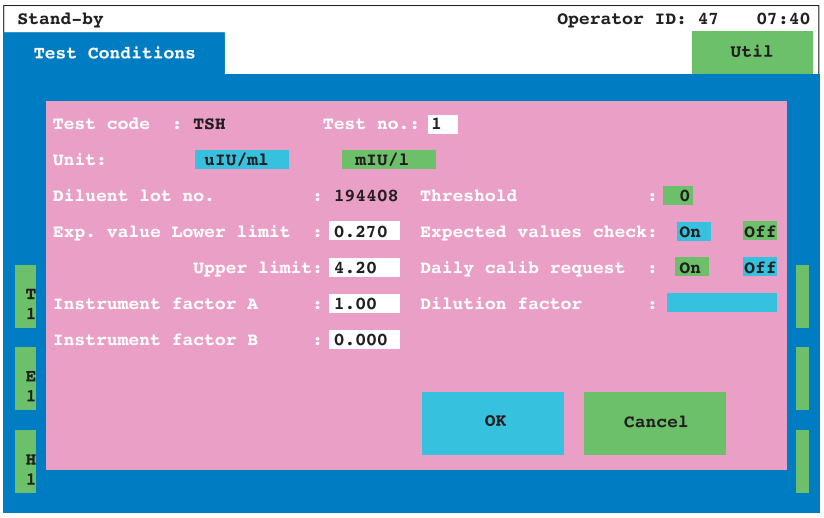
Procedure

Follow the instructions to change an assay's expected values and/or unit of measure.

STEP	ACTION
1	Touch Util to access the UTIL screen.



3.13 How To Change Expected Values

STEP	ACTION
2	Touch Test Conditions to access the TEST CONDITIONS screen. 
3	Touch the test button for which you want to change the expected values. Touching the test button accesses the 'Test Conditions Details' pop-up window. 
4	If you need to change the unit of measure in addition to the expected values, touch the desired unit. The selected unit appears in a light blue field.

3.13 How To Change Expected Values

STEP	ACTION
5	Touch the `Lower limit` field and type the value of the new lower limit. Press Enter.
6	Touch the `Upper limit` field and type the value of the new upper limit. Press Enter.
7	Touch OK to accept all changes in the window.

3.14 How To Print Message History

Introduction

One of the first steps in troubleshooting is to print a message history of the past 10 - 20 alarm messages. This information is helpful to both you and Technical Support, if you require help.

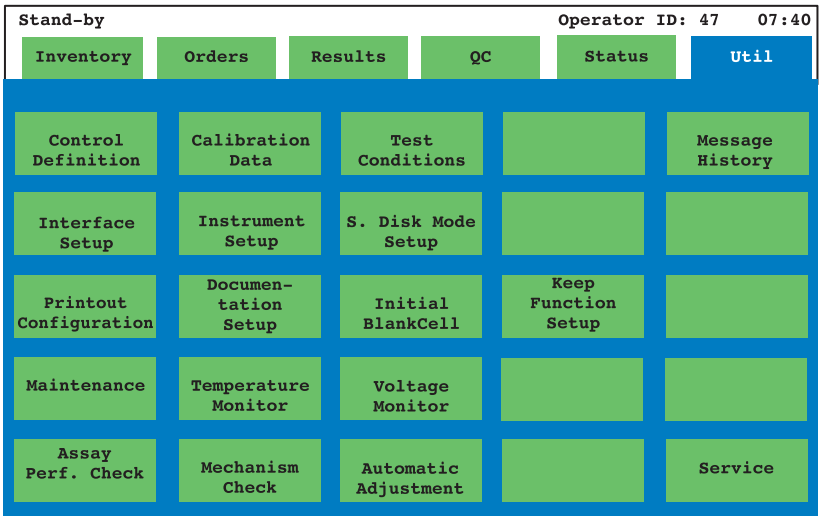
While the screens in the procedure below are for a disk system, the steps involved apply to the disk system and the rack system.

Procedure

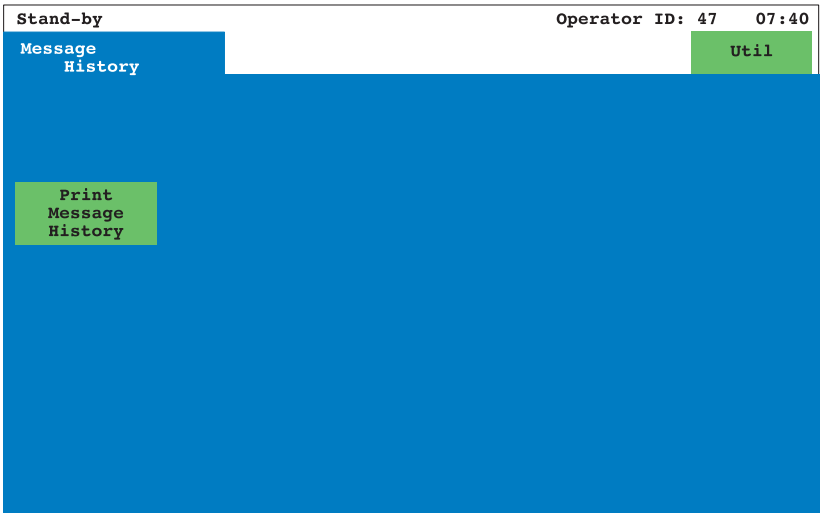
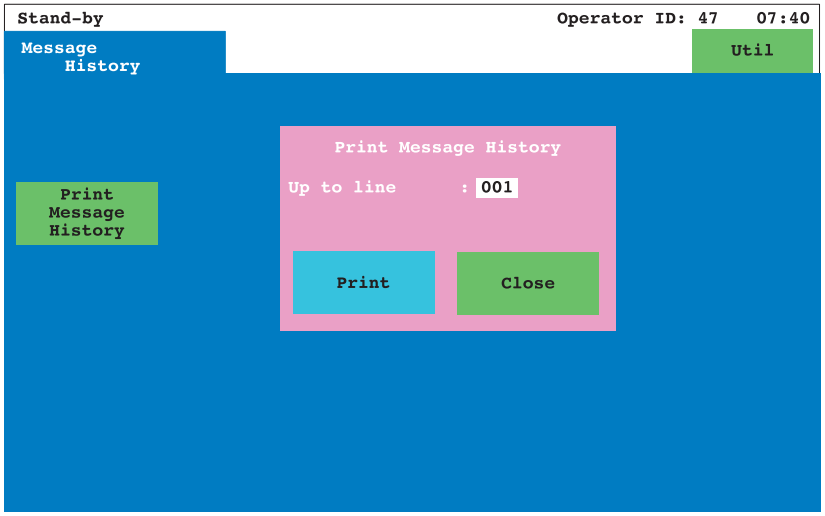
Follow the instructions to print the message history.

Only print the message history when the analyzer is in Stand-by.

STEP	ACTION
1	Touch Util to access the UTIL screen.



3.14 How To Print Message History

STEP	ACTION
2	Touch Message History to access the MESSAGE HISTORY screen. 
3	Touch Print Message History to access the 'Print Message History' pop-up window. 
4	Touch the Up to line field. Type the number of message lines to print. Press Enter. An average number of lines to print is 10 - 20.
5	Touch Print to initiate the report.

3.15 How To Change Printout Configuration

Introduction

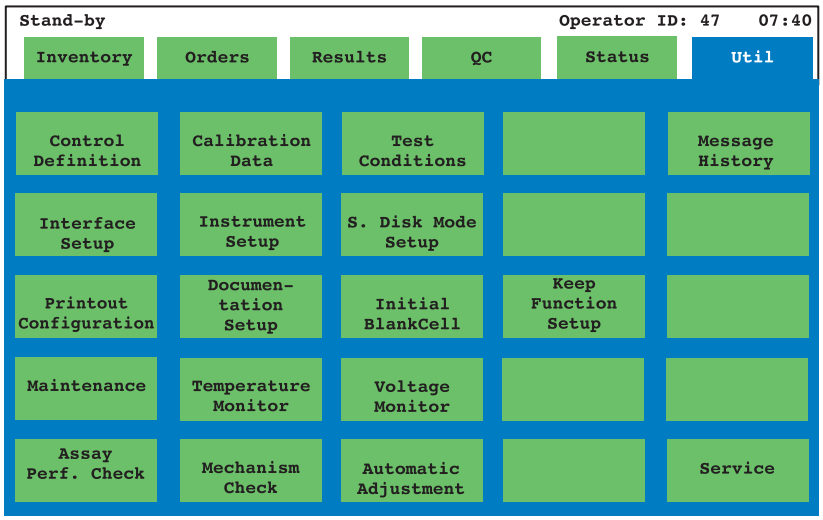
You can change your printout configuration to print either a single sample on a separate sheet of paper, or to print as many samples as possible on a page. The options are “Single” or “Multiple.” You can also select the paper size on which you print your results.

While the screens in the procedure below are for a disk system, the steps involved apply to the disk system and the rack system.

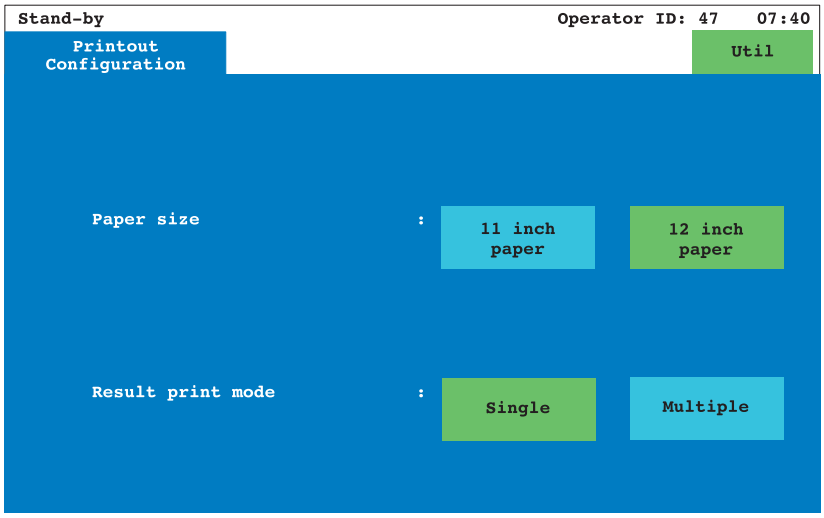
Procedure

Follow the instructions to change the printout configuration.

STEP	ACTION
1	To select the desired printout configuration, touch Util to access the UTIL screen.



3.15 How To Change Printout Configuration

STEP	ACTION
2	Touch Printout Configuration to access the PRINTOUT CONFIGURATION screen. 
2	Touch 11 inch paper or 12 inch paper to select either 11 inch paper or 12 inch paper for reports. The button is light blue when selected.
3	Touch Single or Multiple to select either single or multiple samples per page. The button is light blue when selected.

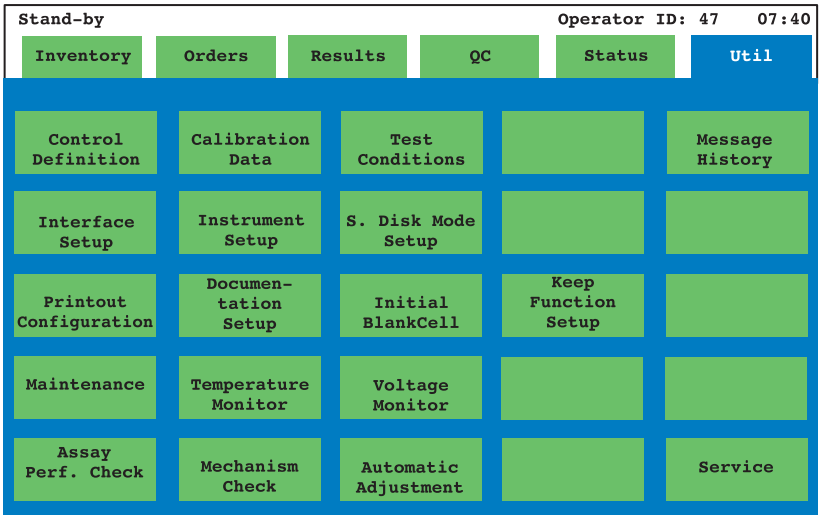
3.16 How To Change the Sample Disk Mode

Introduction

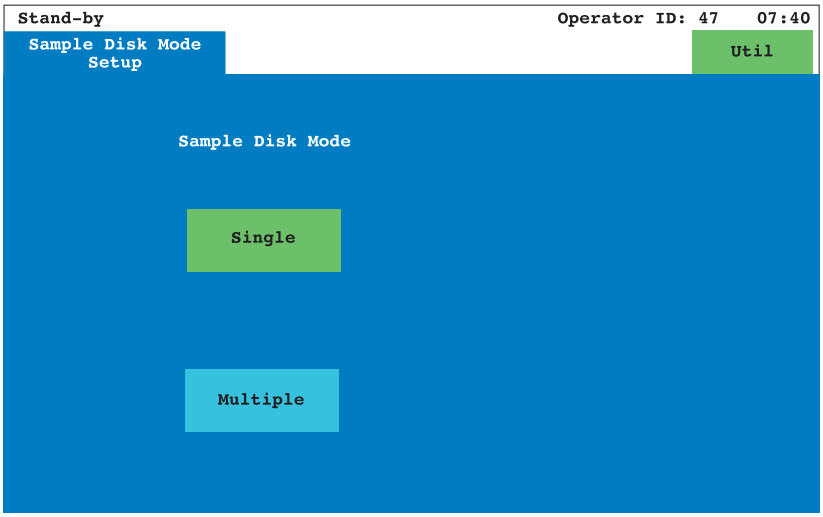
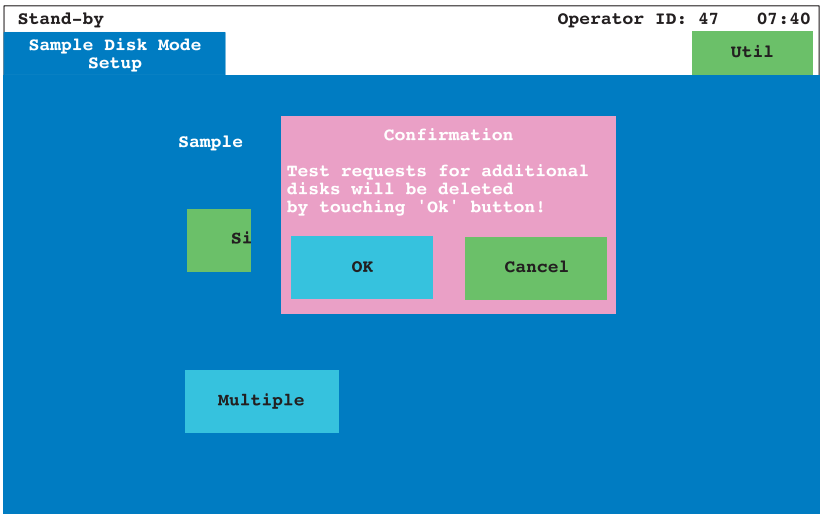
Depending upon your workflow, you must determine the optimal sample disk operating mode to use on the Elecsys 2010. This could be the single disk or multiple disk mode.

Procedure

Follow the instructions to change the sample disk mode.

STEP	ACTION
1	Touch Util to access the UTIL screen. 

3.16 How To Change the Sample Disk Mode

STEP	ACTION
2	Touch S. Disk Mode Setup to access the S. DISK MODE SETUP screen. 
3	Touch the appropriate button to select either single or multiple disk mode. Touching the button accesses the 'Confirmation' pop-up window. The analyzer must be in Stand-by to select a disk mode. 
4	Touch OK to confirm the selected disk mode. *When you change disk modes, all open test requests are deleted. Verify all samples are complete before you change disk operating modes.*

Notes